DATOSPIR-110/120
SPIROMETER

511-800-MU2
Rev: 2.02 • 2013-10

DATOSPIR -110/120 SPIROMETER
*** USER´S MANUAL ***
E. 2.02

Revised
Date: 2013-10

Antoni Picó
Technical Manager

Aproved
Date: 2013-10

Carlos Recio
Sales Manager

CE 0318

PRODUCT CONFORMS WITH
93/42/CEE Medical Devices Directive.
Class II a

SIBEL S.A.
Rosselló, 500
08026 Barcelona
Spain

Tel. : +34 93 436 00 08 Fax : +34 93 436 16 11
e-mail : sibel@sibelmed.com WEB : www.sibelmed.com

AFTER SALES SERVICE
Tel. : +34 93 433 54 50 FAX : +34 93 436 16 11
e-mail : sat@sibelmed.com

SAFETY

SPECIAL PRECAUTIONS

The spirometer DATOSPIR-110/120 has been designed to have the maximum safety. All the operation instructions must be read before starting the DATOSPIR-110/120. Otherwise, injures to the user or the patient and damage to the device and/or accessories might occur.

EXPECTED USAGE

The spirometer measures and calculates a long list of human respiratory function parameters.

The spirometer is designed to be used exclusively by health care personnel, being supervised and trained by a doctor.

The spirometer is not designed to be used in open air conditions, or under any other conditions or energy supply not foreseen in this manual.

PATIENT'S EFFECTS IN THE SPIROMETER USAGE

Spirometry tests require the patient's collaboration, the patient must perform a complete forced expiration to be able to get meaningful FVC values. The doctor should assess the patient's capacity to perform the spirometry tests. Special precaution must be taken with children, elderly people and disabled people.

LIMITATIONS OF USE. CONTRAINDICATIONS

An spirometry test results analysis is not enough for itself to carry out an accurate diagnosis on the patient's clinical condition, therefore it must be completed with the clinical history and those tests the doctor considers necessary.

The tests interpretation and the derived treatments must be performed by a doctor.

The patient's symptoms before the execution of any spirometry test must be considered by health care personnel.
Health care personnel is responsible of the acceptability of a test.

The spirometer must not be used when results validity might be probably compromised due to external factors.

Take care NOT to place the equipment where it could be splashed by water or other liquids or cover it with objects that prevent air from circulating around it while it is running.

The device should NOT be used stacked or adjacent to other equipment.

The equipment must be stored and used within the temperature, pressure and humidity ranges specified in this manual.

ELECTRICAL RISKS

DO NOT remove the device or accessories cover. Servicing and repair of the apparatus must only be carried out by trained personnel. Contact with the voltage inside the system can cause serious injury.

DO NOT use damaged transducers, accessories or cables.

DO NOT submerge the device parts in any liquid. IT CAN RESULT IN ELECTRICAL DISCHARGE. Consult the equipment cleaning method in Chapter 8, Section 8.1. UPKEEP, PREVENTATIVE AND CORRECTIVE MAINTENANCE.

To ensure vital safety features under the EN 60601.1 standard, only equipment compliant with the electrical safety standards in force may be connected to this device. To connect DATOSPIR 110/120 to a non-medical device with ground conductor, you must install an additional ground conductor to the non medical device.

DO NOT use multiple mains sockets, unless they comply with EN-60601-1. They can degrade electrical safety.

DO NOT submerge the transducers connectors in any liquid. THIS CAN RESULT IN ELECTRICAL DISCHARGE.

EXPLOSION RISKS

DO NOT uses the device in presence of anaesthetics or flammable gases. **IT CAN RESULT IN EXPLOSION**.

RISKS OF CONTAMINATION

To avoid the risk of contamination or cross infection, the Turbine and Fleisch transducers must be cleaned/disinfected before use (Consult the section UPKEEP, PREVENTIVE AND CORRECTIVE MAINTENANCE).

Reusable mouthpieces must also be disinfected. Disposable transducers and disposable mouthpieces must not be reused.

RISKS OF INTERFERENCE

This is an electronic product, so high frequency emissions can interfere with the correct use. For this reason, the products which can generate interferences (radios, cellular phones, etc.) should be kept apart.

The portable or mobile radiofrequency devices can affect the normal functioning of the electronic medical devices.

This is a medical electronic device and as such it needs special precautions regarding the electromagnetic compatibility (EMC) and it should be installed and setup according to the EMC information attached (See Appendix 1. ELECTROMAGNETIC COMPATIBILITY).

The use of transducers, accessories and cables different to the ones specified here, except the transducers and cables sold by the manufacturer as spare parts, could adversely affect patient safety, cause a malfunction of the equipment and/or produce an increase of the emissions or a decrease in the device immunity.

REMOVAL OF WASTE FROM ELECTRICAL AND ELECTRONIC APPLIANCES BY DOMESTIC USERS IN THE EUROPEAN UNION

This symbol on the product indicates that you cannot dispose of the product with domestic waste.

However, any removal of this type of waste is the responsibility of the user and must be taken to a designated collection point for the recycling of electrical and electronic appliances. The separate recycling and collection of this waste at the time of removal will help preserve natural resources and ensure that recycling protects your health and the environment. Should you require further information on the places where you can leave this waste for recycling, contact the local authorities in your town or city, the domestic waste management service or the distributor who sold you the product.

1. INSTRUCTIONS FOR USE AND INSTALLATION

1.1. INTRODUCTION

The spirometer **DATOSPIR-110/120** is a compact device based on different types of transducers. (Fleisch, turbine and/or disposable), a wide liquid crystal backlighted screen and an internal or external printer. It can incorporate a module for measuring the Maximal Inspiratory and Expiratory Pressures (MIP-MEP) and another module for Pulse oximetry measurements (SpO2). Furthermore, it has the possibility, through an optional software, to connect with a computer PC in real or deferred time, in order to perform the spirometric tests with the PC support, to store the performed tests, or to transfer information by other means. All the system is controlled by a microprocessor for the acquisition, calculation and display of alphanumeric and graphic data.

The **DATOSPIR-110/120** series has four models, depending on the options incorporated, as detailed below.

The spirometer **DATOSPIR-110/120** has been developed by the **R+D Department of SIBEL S.A.** in collaboration with **Laboratorio de Función Pulmonar del Hospital de la Santa Creu y Sant Pau de Barcelona**. The device meets the criteria of standardisation of International Institutions: **ATS/ERS** (American Thoracic Society/ European Respiratory Society), etc; as well as Local Institutions: **SEPAR** (Sociedad Española de Neumología y Cirugía Torácica), etc.

The spirometer **DATOSPIR-110/120** has been designed and manufactured according to the Quality Manual of **SIBEL S.A.** which meets the quality regulations **EN 46001 and ISO 9001**, as well as the **Medical Device Directive 93/42/EEC**. According to this directive the device is **Class IIa**.
It also applies the standards of Electric Safety **EN 60601.1, IEC 601.1, UNE 20-613-1** and the Electromagnetic Compatibility standards **EN 60601.1.2 and EN 55011 Group I Class B**.

1.2. PREVIEW OBSERVATIONS

This User Manual is oriented to all the models and options which can compose the spirometer DATOSPIR-110/120. In each case only the corresponding options or functions of the available model will be applied.

This spirometer is manufactured with professional solid components, under strict quality controls. Nevertheless, accidents might happen in the transportation or storage of the devices. It is convenient to make an initial check up of its condition before installing it, as well as of its accessories.

WARNING

IF ANY DAMAGE IN THE PACKAGING IS DETECTED, CONTACT IMMEDIATELY WITH THE TRANSPORT AGENCY, AND YOUR DISTRIBUTOR, BEFORE INSTALLING IT. DO NOT THROW AWAY THE PACKAGING, BAGS, ETC. UNTIL THE CORRECT FUCTIONING OF THE DEVICE IS VERIFIED.

1.3. MODELS OF SPIROMETER DATOSPIR-110/120

The DATOSPIR-110/120 spirometer series consist of different models, depending on the options incorporated,

DATOSPIR-120 A	**DATOSPIR-110 A**
DATOSPIR-120 B	**DATOSPIR-110 C**
DATOSPIR-120 C	
DATOSPIR-120 D	

The enclosed tables show the basic characteristics included in each model as a **stan-dard** and the other parts or functions that can be included as **optional**.

At any moment, if preferred, a certain model can be converted into another superior model, by adding the corresponding parts. In this case, contact with the Sales Dept. of **SIBEL S.A.** or your distributor.

The **DATOSPIR-110** has exactly the same **STANDARD ACCESSORIES** than the DATOSPIR-120, knowing that the DATOSPIR-110 cannot have neither the Fleisch nor the Turbine transducers.

RELACIÓN DE CONTENIDO / PACKING LIST

DATOSPIR 110

511-808-020 REV. 2.01

2012-05

MODELOS / *MODELS*

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	C
_____	1	**DATOSPIR 110 MODELO/*MODEL*** **SN 118-**		
02692	1	PINZA NASAL / *NOSE CLIP*		
_____	1	DATOSPIR-110/120 MANUAL DE USO (Doc. 511-800-MU1) / *DATOSPIR-110/120 USER MANUAL (Doc.* 511-800-MU2)		
01208 07536 (1)	1	ALIMENTADOR EXTERNO / *EXTERNAL POWER SUPPLY* 220V		
02635	2	PAPEL TERMOSENSIBLE / *THERMOSENSITIVE PAPER* 50x57 25m		
02634	2	PAPEL TERMOSENSIBLE / *THERMOSENSITIVE PAPER* 50x110 25m		
02224	1	CONEXIÓN CON PC / *PC CONNECTION LINK*		
02305	**1**	**LICENCIA SOFTWARE ESPIROMETRÍA W-20** ***SPIROMETRY LICENSE SOFTWARE W-20*** • SOFTWARE W-20 (CD) - 511-8FA		
02269 02345 03169 01150	**1** 1 50 1	**TRANSDUCTOR DESECHABLE Compuesto por :** ***DISPOSABLE TRANSDUCER Including:*** • MANGO TRANSDUCTOR DESECHABLE *DISPOSABLE TRANSDUCER HANDLE* • TRANSDUCTOR DESECHABLE / *DISPOSABLE TRANSDUCER* • ADAPTADOR CALIBRACIÓN / *CALIBRATION ADAPTER*		
02484 07266 01566 _____	**1** 1 1 1	**MÓDULO PIM-PEM Compuesto por :** ***MEP-MIP MODULE Including:*** • SONDA OBTURADORA PIM-PEM / *MEP-MIP SHUTTER PROBE* • BOQUILLA MULTIUSO ADULTOS *MULTIUSE ADULTS MOUTHPIECE* • MANUAL DE USO, ANEXO PIM-PEM (Doc. 511-8D0-MU1) *ANNEX MEP-MIP USER MANUAL (Doc. 511-8D0-MU2)*		
02446	1	**SONDA SNIF PARA ADULTOS / *SNIF PROBE FOR ADULTS*** Requiere PLACA PIM-PEM / *MIP-MEP BOARD required*		
06998 07266 04108	1 1 1 1	**MÓDULO SNIF Compuesto por :** ***SNIF MODULE Including:*** • SONDA SNIF PARA ADULTOS / *SNIF PROBE FOR ADULTS* • PLACA PIM-PEM/ *MIP-MEP BOARD* • INTERCONEXIÓN PIM-PEM / *MIP-MEP CONNECTION*		
02487 01846 _____	**1** 1 1	**MÓDULO PULSIOXIMETRIA Compuesto por :** ***PULSE OXIMETRY MODULE Including:*** • SENSOR PULSIOXIMETRIA SPO_2 *PULSE OXIMETRY SPO_2 SENSOR* • MANUAL DE USO, ANEXO SPO_2 (Doc. 511-890-MU1) *ANNEX SPO_2 USER MANUAL (Doc. 511-890-MU2)*		

RELACIÓN DE CONTENIDO / PACKING LIST

DATOSPIR 110

511-808-020 REV. 2.01

2012-05

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	C
07182	1	CABLE IMPRESORA PARALELO-CENTRONICS *CENTRONICS-PARALLEL PRINTER CABLE*		
02483 (2)	1	MODULO ESTACIÓN METEOROLÓGICA (2) *METEOROLOGICAL STATION MODULE*		
01497	1	BATERÍA RECARGABLE / *RECHARGEABLE BATTERY* Ni-Cd 12V 1.5A		
01502	1	BOLSA DE TRANSPORTE / *CARRYING BAG*		
01207 07535 (1)	1	ALIMENTADOR EXTERNO / *EXTERNAL POWER SUPPLY* 100/130V		
02738	1	OPCIÓN SOFTWARE PRUEBAS BRONCOCONSTRICCIÓN *BRONCHOCONSTRICTION TESTS SOFTWARE OPTION*		
02205	1	OPCIÓN SOFTWARE INCENTIVO GRÁFICO NIÑOS *INCENTIVE GRAPHIC FOR CHILDREN SOFTWARE OPTION*		■
01480	1	OPCIÓN SOFTWARE BASE DE DATOS +150 PRUEBAS *INTERNAL DATABASE (+150 TESTS) SOFTWARE OPTION*		■
01481	1	OPCIÓN SOFTWARE BASE DE DATOS +500 PRUEBAS *INTERNAL DATABASE (+500 TESTS) SOFTWARE OPTION*		
01805	1	OPCIÓN SOFTWARE CONEXIÓN A IMPRESORA EXTERNA *CONNECTION TO EXTERNAL PRINTER SOFTWARE OPTION*		■
03031	1	OPCIÓN PULSIOXIMETRIA SOFTWARE W-20 *PULSEOXIMETRY W-20 SOFTWARE OPTION*		
03030	1	OPCIÓN PIM-PEM SOFTWARE W-20 *MEP-MIP W-20 SOFTWARE OPTION*		
03028	1	OPCIÓN BRONCOCONSTRICCIÓN SOFTWARE W-20 *BRONCHOCONSTRICTION W-20 SOFTWARE OPTION*		

■ STANDARD ☐ OPCIONAL / *OPTIONAL* --- NO DISPONIBLE / *NOT AVAILABLE*

(1) Alimentador externo para opción SpO2 (sin interruptor) /
Power supply for SpO2 option (without switch)

(2) El módulo estación meteorológica no es compatible con la opción SpO2 /
The wether station module is not compatible with the SPO2 option

NOTA: EN CASO DE INCLUIRSE DE SERIE DOS MÓDULOS QUE IMPLIQUEN LA INCLUSIÓN DEL MISMO ELEMENTO (POR EJEMPLO EL ELEMENTO 140-550-010 EN LOS MÓDULOS DE FLEISCH Y TURBINA), SOLAMENTE SE INCLUIRÁ UNO.

- LOS ARTÍCULOS Y CANTIDADES RELACIONADAS ANTERIORMENTE HAN SIDO CUIDADOSAMENTE COMPROBADAS. EN CASO DE FALTAS O DESPERFECTOS PROCEDAN A COMUNICÁRNOSLO LO MAS PRONTO POSIBLE.
- SI DETECTA ALGÚN DETERIORO EN EL EMBALAJE, CONTACTE INMEDIATAMENTE CON LA AGENCIA DE TRANSPORTE Y CON SU DISTRIBUIDOR ANTES DE PROCEDER A INSTALARLO. NO SE DEBE DESPRENDER DE LOS EMBALAJES, BOLSAS, ETC. HASTA QUE VERIFIQUE TOTALMENTE EL CORRECTO FUNCIONAMIENTO DEL EQUIPO.
- SÍRVANSE DEVOLVERNOS UNA COPIA DEL ALBARAN SELLADA Y FIRMADA.

RELACIÓN DE CONTENIDO / PACKING LIST

DATOSPIR 120

511-808-010 REV. 2.01

2012-05

MODELOS / *MODELS*

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	B	C	D
_____	1	**DATOSPIR 120 MODELO / *MODEL*** **SN: 118-**				
01555	100	BOQUILLA CARTÓN DESECHABLE / *DISPOSABLE MOUTHPIECE*	■	■	■	■
02692	1	PINZA NASAL / *NOSE CLIP*	■	■	■	■
_____	1	DATOSPIR-110/120 MANUAL DE USO (Doc. 511-800-MU1) / *DATOSPIR-110/120 USER MANUAL (Doc.* 511-800-MU2)	■	■	■	■
01208 07536 (1)	1	ALIMENTADOR EXTERNO / *EXTERNAL POWER SUPPLY* 220V	■	■	■	■
02635	2	PAPEL TERMOSENSIBLE / *THERMOSENSITIVE PAPER* 50x57 25m	■			
02634	2	PAPEL TERMOSENSIBLE / *THERMOSENSITIVE PAPER* 50x110 25m		■	■	■
03165 07425 01305 01809 01172	**1** 1 1 1 1	**TRANSDUCTOR TIPO TURBINA Compuesto por :** ***TURBINE TRANSDUCER Including:*** • MANGO ALOJAMIENTO TURBINA *TURBINE HANDLE HOUSING* • TURBINA / *TURBINE* • CABLE TELEFONICO / *TELEPHONIC CABLE* 3.5m • ADAPTADOR TELEFONICO A DB15 *TELEPHONIC ADAPTER A DB15*	■	■		
03171 02339 02534 01823 01563 03065	**1** 1 1 2 2 1	**NEUMOTACÓMETRO TIPO FLEISCH Compuesto por :** ***FLEISCH NEUMOTACHOMETER Including:*** • MANGO NEUMOTACÓMETRO FLEISCH *FLEISCH NEUMOTACHOMETER HANDLE* • NÚCLEO NEUMOTACÓMETRO / *NEUMOTACHOMETER CORE* • CONO LINEALIZADOR / *LINEARIZER CONE* • BOQUILLA GOMA NEUMOTACÓMETRO *NEUMOTACHOMETER RUBBER MOUTHPIECE* • SOPORTE NEUMOTACÓMETRO *NEUMOTACHOMETER HOLDER*			■	■
02224	1	CONEXIÓN CON PC / *PC CONNECTION LINK*	■	■	■	■
02305 _____	**1** 1	**LICENCIA SOFTWARE ESPIROMETRÍA W-20** ***SPIROMETRY LICENSE SOFTWARE W-20*** • MANUAL DE USO (Doc. 511-8F0-MU1) / *USER MANUAL* SOFTWARE W-20 (Doc. 511-8F0-MU2) **NO INCLUIR EL CABLE CON LLAVE**	■	■	■	■
02484 07266 01566 _____	**1** 1 1 1	**MÓDULO PIM-PEM Compuesto por :** ***MEP-MIP MODULE Including:*** • SONDA OBTURADORA PIM-PEM / *MEP-MIP SHUTTER PROBE* • BOQUILLA MULTIUSOS ADULTOS *MULTIUSE ADULTS MOUTHPIECE* • MANUAL DE USO, ANEXO PIM-PEM (Doc. 511-8D0-MU1) *ANNEX MEP-MIP USER MANUAL (Doc. 511-8D0-MU2)*				
02446	1	**SONDA SNIF PARA ADULTOS / *SNIF PROBE FOR ADULTS*** Requiere PLACA PIM-PEM / *MIP-MEP BOARD required*				

RELACIÓN DE CONTENIDO / PACKING LIST

DATOSPIR 120

511-808-010 REV. 2.01

2012-05

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	A	B	C	D
06998 07266 04108	1 1 1 1	**MÓDULO SNIF Compuesto por :** ***SNIF MODULE Including:*** • SONDA SNIF PARA ADULTOS / *SNIF PROBE FOR ADULTS* • PLACA PIM-PEM/ *MIP-MEP BOARD* • INTERCONEXIÓN PIM-PEM / *MIP-MEP CONNECTION*				
02487 01846	**1** 1 1	**MÓDULO PULSIOXIMETRIA Compuesto por :** ***PULSE OXIMETRY MODULE Including:*** • SENSOR PULSIOXIMETRIA SPO_2 *PULSE OXIMETRY SPO_2 SENSOR* • MANUAL DE USO, ANEXO SPO_2 (Doc. 511-890-MU1) *ANNEX SPO_2 USER MANUAL (Doc. 511-890-MU2)*				
02269 02345 03169 01150	 1 50 1	**TRANSDUCTOR DESECHABLE Compuesto por :** ***DISPOSABLE TRANSDUCER Including:*** • MANGO TRANSDUCTOR DESECHABLE *DISPOSABLE TRANSDUCER HANDLE* • TRANSDUCTOR DESECHABLE / *DISPOSABLE TRANSDUCER* • ADAPTADOR CALIBRACIÓN / *CALIBRATION ADAPTER*				
07182	1	CABLE IMPRESORA PARALELO-CENTRONICS *CENTRONICS-PARALLEL PRINTER CABLE*				
02483 (2)	1	MODULO ESTACIÓN METEOROLÓGICA (2) *METEREOLOGICAL STATION MODULE*				■
01497	1	BATERÍA RECARGABLE / *RECHARGEABLE BATTERY* Ni-Cd 12V 1.5A				
01502	1	BOLSA DE TRANSPORTE / *CARRYING BAG*				
01207 07535 (1)	1	ALIMENTADOR EXTERNO / *EXTERNAL POWER SUPPLY* 100/130V				
02738	1	OPCIÓN SOFTWARE PRUEBAS BRONCOCONSTRICCIÓN *BRONCHOCONSTRICTION TESTS SOFTWARE OPTION*				■
02205	1	OPCIÓN SOFTWARE INCENTIVO GRÁFICO NIÑOS *INCENTIVE GRAPHIC FOR CHILDREN SOFTWARE OPTION*		■	■	■
01480	1	OPCIÓN SOFTWARE BASE DE DATOS +150 PRUEBAS *INTERNAL DATABASE (+150 TESTS) SOFTWARE OPTION*		■	■	
01481	1	OPCIÓN SOFTWARE BASE DE DATOS +500 PRUEBAS *INTERNAL DATABASE (+500 TESTS) SOFTWARE OPTION*				■
01805	1	OPCIÓN SOFTWARE CONEXIÓN A IMPRESORA EXTERNA *CONNECTION TO EXTERNAL PRINTER SOFTWARE OPTION*			■	■
03031	1	OPCIÓN PULSIOXIMETRIA SOFTWARE W-20 *PULSEOXIMETRY W-20 SOFTWARE OPTION*				
03030	1	OPCIÓN PIM-PEM SOFTWARE W-20 *MEP-MIP W-20 SOFTWARE OPTION*				
03028	1	OPCIÓN BRONCOCONSTRICCIÓN SOFTWARE W-20 *BRONCHOCONSTRICTION W-20 SOFTWARE OPTION*				

■ STANDARD / ☐ OPCIONAL / *OPTIONAL* --- NO DISPONIBLE / *NOT AVAILABLE*

WARNING

According to different standards and specially the Medical Device Directive 93/42/ECC, it is advisable to verify and/or calibrate the electromedical devices periodically in order to guarantee the reliability of their functions and the safety of the patient, user and environment.

The spirometer DATOSPIR-110/120 must have done, besides routine calibrations, a general check up of its safety systems, adjustments, functions, etc. with a yearly periodicity. Do not pass in any case more than eighteen months without doing it. The check-up must be done at any moment when the incorrect functioning of the device is suspected.

These check ups must be done according to the Verifying and Adjustment Manufacturer Procedures (SIBEL S.A.), by the manufacturer or qualified technical staff and authorised by SIBEL S.A.
The accessories, spare parts, etc. must be the original ones, and they will be ordered to the manufacturer or authorise ddistributor, so as to guarantee the correct functioning of the spirometer.

MANUFACTURER RESPONSIBILITY

SIBEL S.A. is responsible for the safety, reliability and functioning of this device only if:

- The place where the device is installed meets the requirements of electrical installation IEC, as well as the rest of standards applicable, if it is connected to the mains.

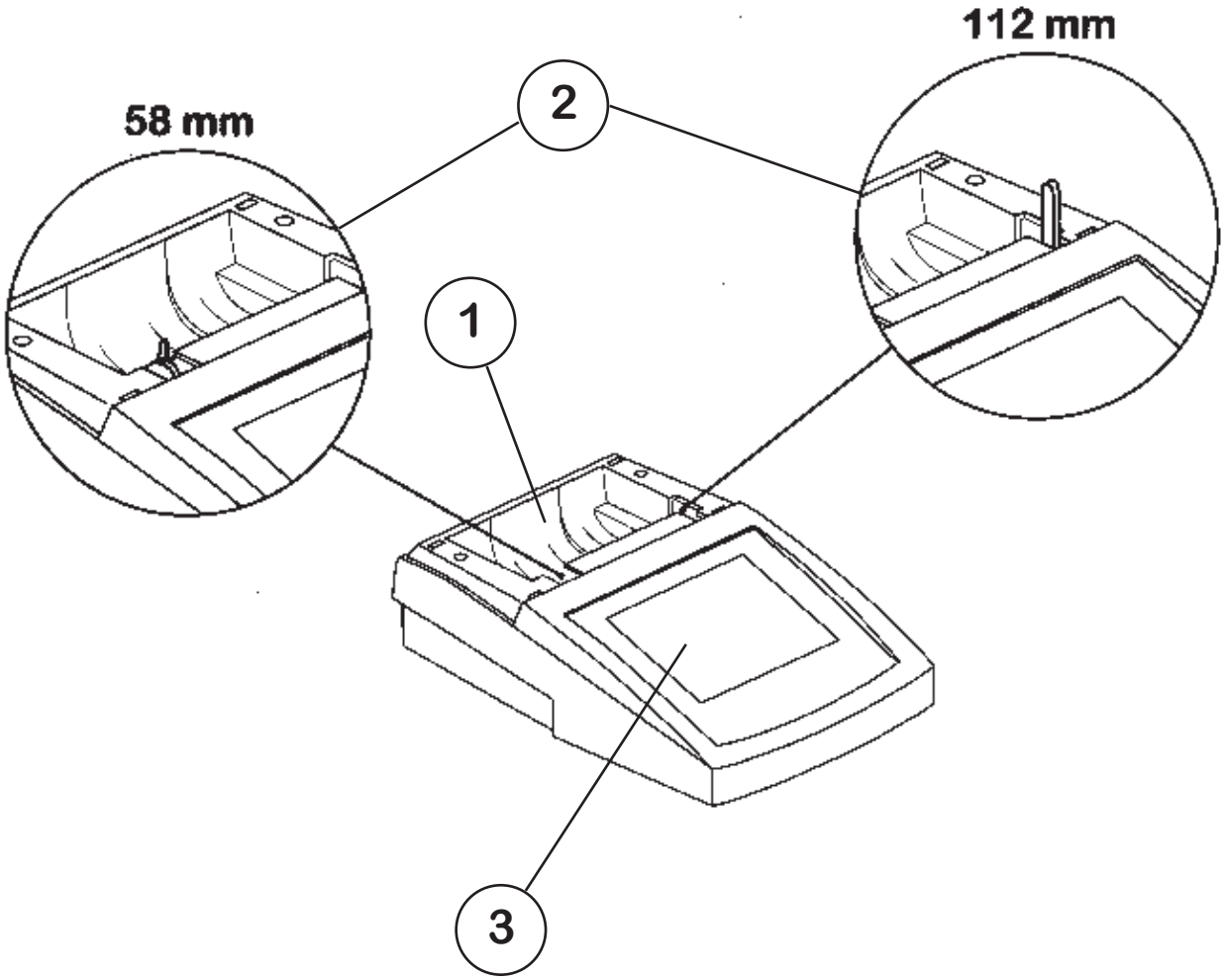
- The reparations, checks or modifications, during the guarantee period or not, are carried out by the technical staff of SIBEL S.A.

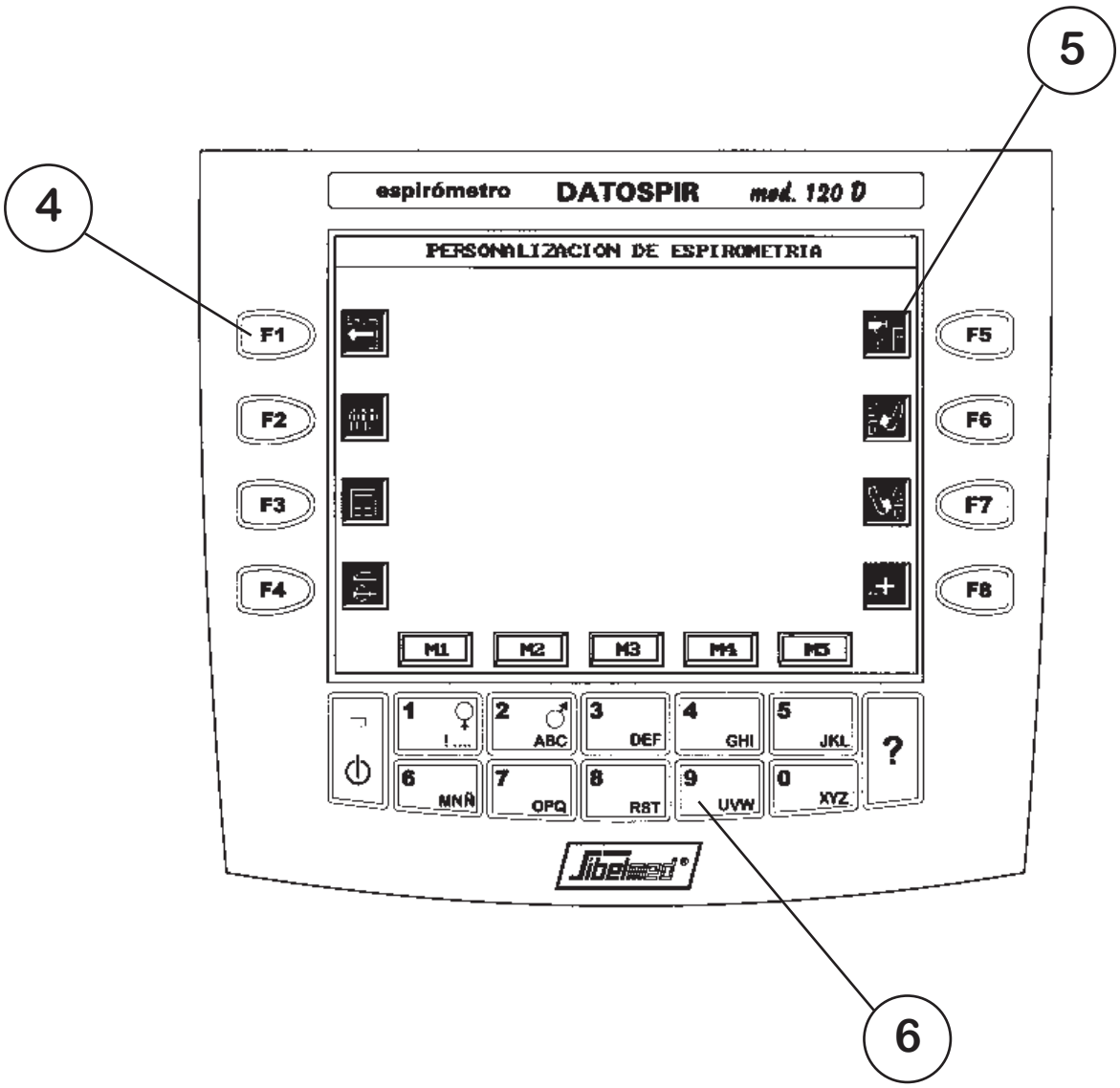
- The device is used by qualified personnel and according to the recommendations of this Use Manual.

1.4. DISTRIBUTION OF CONTROLS, INDICATORS AND CONNECTORS

1.4.1. GENERAL PANNEL

No. 1
Housing of paper and internal printer of 112 or 58 mm.
No. 2
Lever to lock or unlock the pull paper roll.
No. 3
Backlighted liquid crystal display of 320 x 240 pixels.



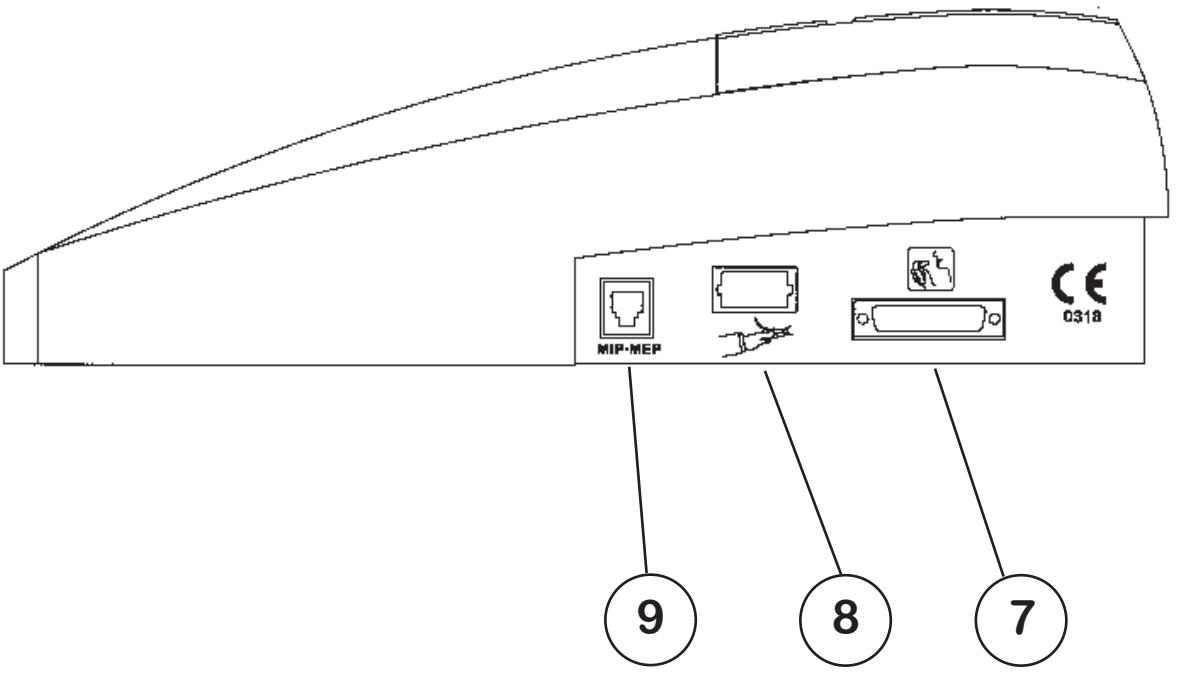


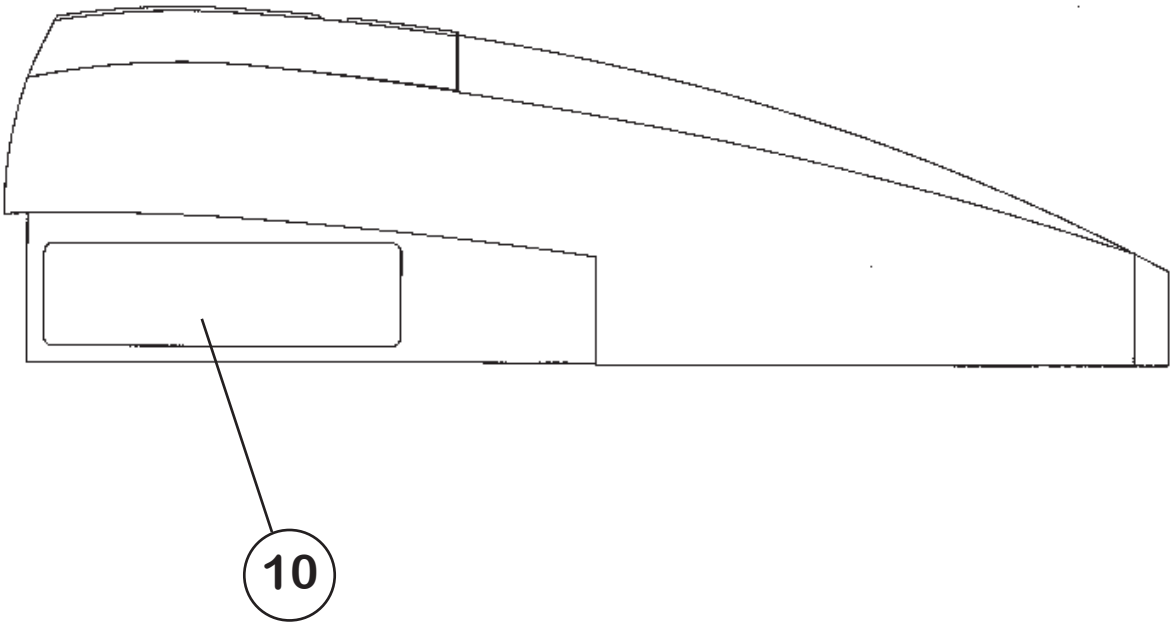
No. 4
Function keys F1 to F8 for handling the device.
No. 5
Graphic icons indicating the functions.
No. 6
Keyboard of tactile membrane with:

- Stop / Start Key
- Light indicator type LED to start and other functions
- Alphanumeric keyboard
- ? - Key to display help on the screen

1.4.2. RIGHT AND LEFT SIDE

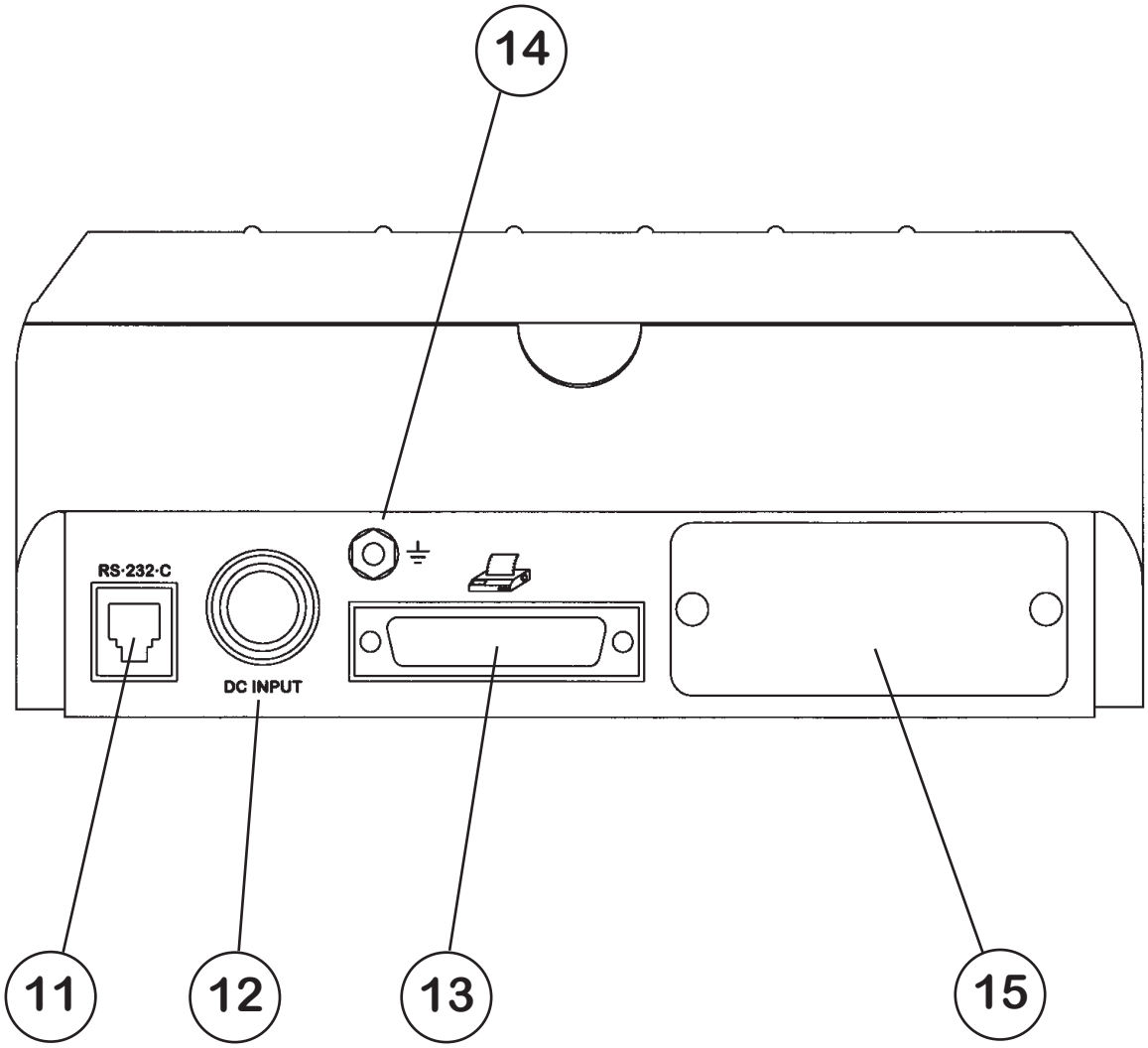
No. 7
Connection of the spirometric transducer
No. 8
Connection of the pulse oximetry sensor SpO2
No. 9
Connection of the Maximal Respiratory Pressures MIP-MEP
No. 10
Characteristics board





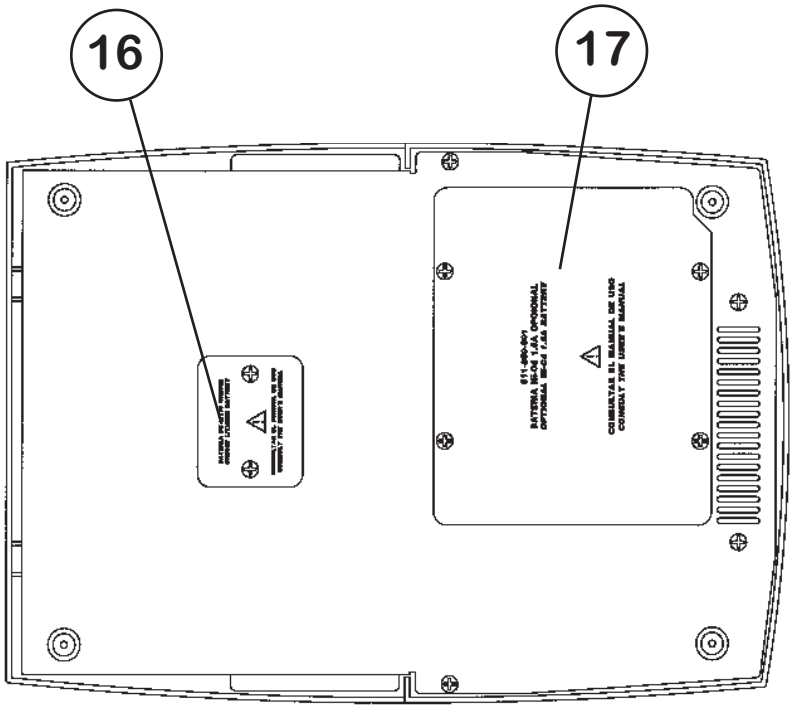
1.4.3. BACK PANNEL

No. 11
Serial communications channel RS-232C
No. 12
Connection to the mains power supply.
No. 13
Connection for external parallel printer
No. 14
Base for the connection of additional protection
No. 15
Housing for the Electronic Weather Station



1.4.4. BASE OF THE DEVICE

No. 16
Housing of the lithium type battery CR2032
No. 17
Housing of the Ni-Cd battery of 12 V 1,5 Ah

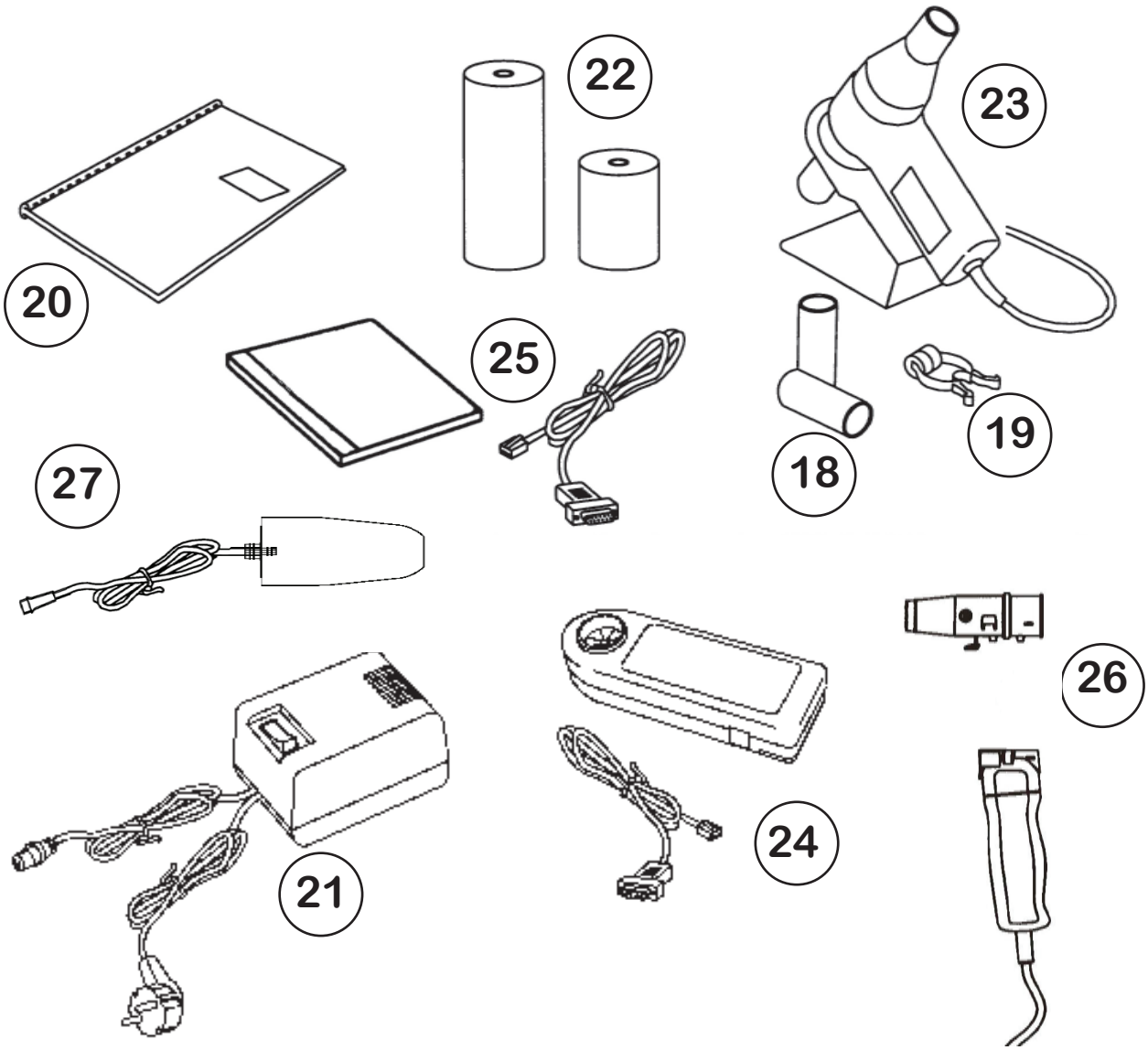


1.4.5. STANDARD ACCESSORIES

No. 18
Disposable mouthpiece
No. 19
Nose clip
No. 20
Use Manual
No. 21
Mains power supply
No. 22
Thermal paper of 57 or 111 mm
No. 23
Neumotachometer type Fleisch with holder
No. 24
Transducer with turbine
No. 25
Spirometry Software W-20 DEMO and Connection
No. 26
Handle and Disposable Transducer

IMPORTANT

TO TAKE OUT THE LITHIUM BATTERY KEEP THE EQUIPMENT WORKING. IF YOU TAKE IT OUT WITH THE EQUIPMENT TURNED OFF, THE CALIBRATION FACTORS WILL BE LOST.



1.4.6. OPTIONAL ACCESSORIES (depending on model)

Spirometry Software W-20 license

Accessories option MIP-MEP

Accessories option pulse oximetry SpO2

Transducer type disposable with holder

Transport bag

Calibration syringe

1.5. INSTALLATION AND SET UP

1.5.1. INSTALLATION

The spirometer **DATOSPIR-110/120** is **CLASS IIa** according to the criteria of **European Directive for Medical Devices 93/42/EEC**. According to the type of protection against electric discharges established in the norm **EN60601.1**, is classified as **CLASS I type B**.

The spirometer **DATOSPIR-110/120** works in standard mode with an external power supply, which is connected to the mains power, of **200 to 240 V 50/60 Hz** with earth inlet (100 to 130 V 50/60 Hz can also be ordered) or optionally with a rechargeable internal battery, with exception of the models with Fleisch neumotachometer.

Do not charge other type of batteries, they could explode.
If you are not going to use the device for a while, remove the battery to avoid they could spill its substances.

The maximal power required (including the heater of Fleisch neumotachometer), is under 25 VA.

Internal battery

The consumption of electrical power that the device needs, specially by the backlight of the large LCD, limits the battery duration. Therefore, it is recommended to use this functioning mode only in emergency cases or in places that do not have mains power supply.

The battery is Ni-Cd 12V 1.5Ah and offers an autonomy of 1.5 hours approximately. The charging time is about 16 hours. Remind that if the light of the power supply is on, the battery is charging, even though the device is turned off.

To save power, the device has incorporated two auto-shutdown systems. The first one makes the screen backlight turn off, when **two minutes** pass without any key press. The device sleeps until one key is pressed, recovering the information previously displayed. The second system performs an autoshutdown after **fifteen minutes** without working. In this case, the information on screen is lost. To start the device, follow the normal procedure.

The working ambient conditions are::

- Ambient temperature: from 10ºC to 40 ºC. (American Thoracic Society recommends from 17 to 40 ºC)
- Humidity: <= 85% (without condensation)
- Atmospheric pressure: from 525 to 800 mmHg (de 3000 a - 400 metros aprox.)

-Storage temperature: from -5ºC to 70ºC (Exception: termosensible internal printer paper: from 5ºC to 40ºC

The main power cable includes an earth protecting wire, since it is necessary for the spirometer, as for any other electromedical device CLASS I, according to EN60601.1, to be connected to earth.
Remember not to place the device near the water or other liquids, avoiding to splash over it. Do not cover the device with objects that obstruct the air circulation around it during its functioning.

The sequence of operations to configure the **DATOSPIR-110/120**, in order to perform the spirometric tests is the following:

1st Connect the power supply outlet to the power inlet no. 11.

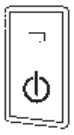
2nd Turn the mains switch of power supply in OFF position “0”.

3rd Connect the power supply to the mains, in accordance with voltage and frequency of the power supply. Turn the mains switch of the power supply in ON position “I” (Light on).

4th Connect the Transducer to the unit through connector Nº 7.

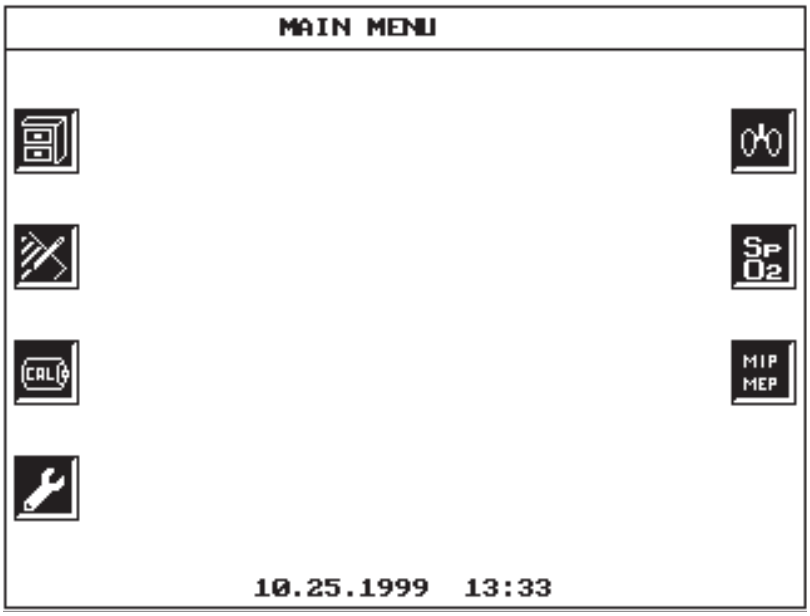
If all these indications are met, the device is ready to be set-up.

1.5.2. SET-UP

For the spirometer set-up, press the key Stop/Start 
Next, the LED indicator is lit, the device emits a “beep” sound and makes an auto-check. For some seconds, the logo “**SIBELMED**” is displayed on the screen, as well as some other information like:

Version of the program
Address of **SIBEL S.A.**
Warnings of auto-check
Warnings of calibration, if proceeds
Warnings of maintenance, if proceeds

Next, the **MAIN MENU** is displayed

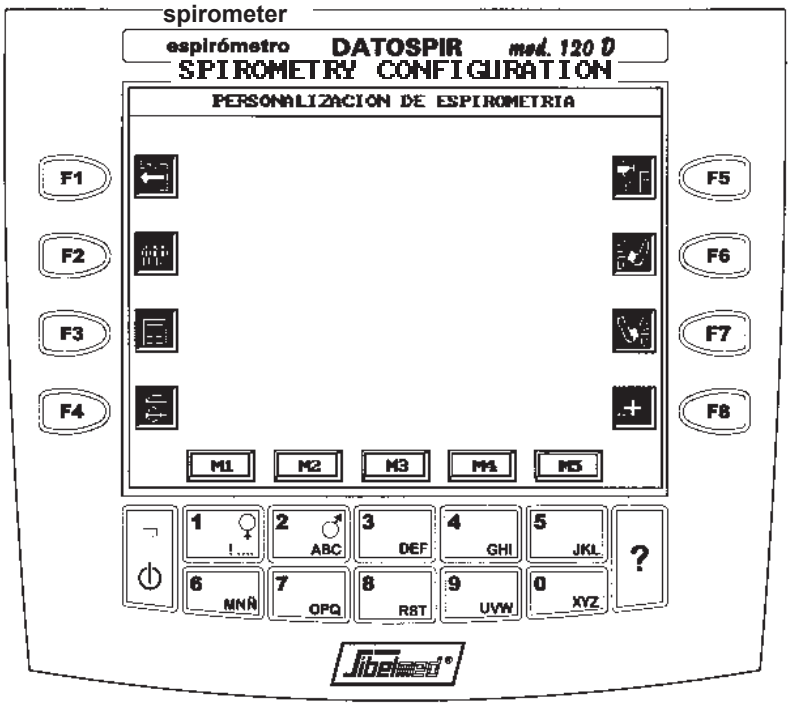


In the lower part of the screen, the clock-calendar with date and time is displayed. It can be updated in the Maintenance Program. The environmental values for Temperature, Pressure and Humidity are also presented, if the corresponding **Electric Weather Station** is available.

1.5.3. OBSERVATIONS ABOUT THE HANDLING OF THE DEVICE

The spirometer development has been carried out prioritising its simple use, so that the user can handle it easy and comfortably. Maybe all the functions of the device seem complex, but due to the conception of the device and its use, the user will realise that the device is extremely easy and intuitive to use for anyone who works

in the health environment.



The disposable transducer incorporates a calibration factor which permits the exchange of the transducer without having to perform any calibration. Each transducer will have associated a correction factor.
When executing each one of the tests, verification that the transducer factor is the same than the one appearing in the unit's display must be done.

All the functions are accessible from the eight keys F1 to F8 located in the left side (F1 to F4) and right (F5 to F8) of the display.

On the bottom of the screen, some icons can appear, which are associated to numeric keys 1 to 5.

Furthermore, the device has a help system on screen, which describes the meaning of each icon briefly, as well as other information that eases the use of the device.

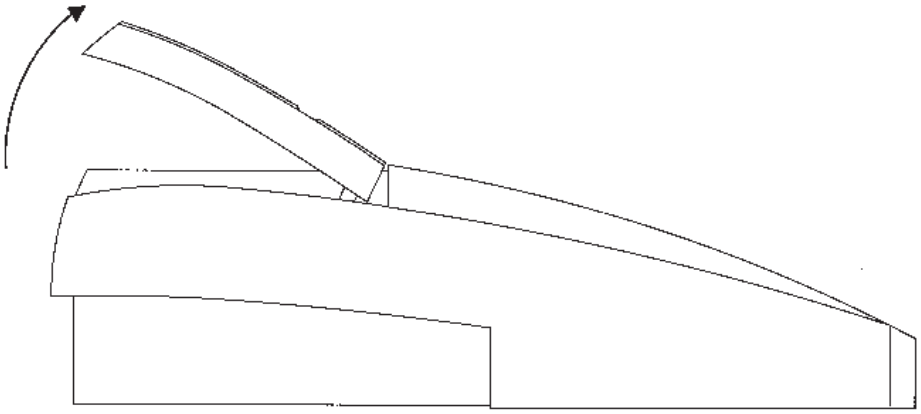
This help is shown by pressing the key "**?**" at any moment.

1.5.4. LOADING THE PAPER IN THE PRINTER

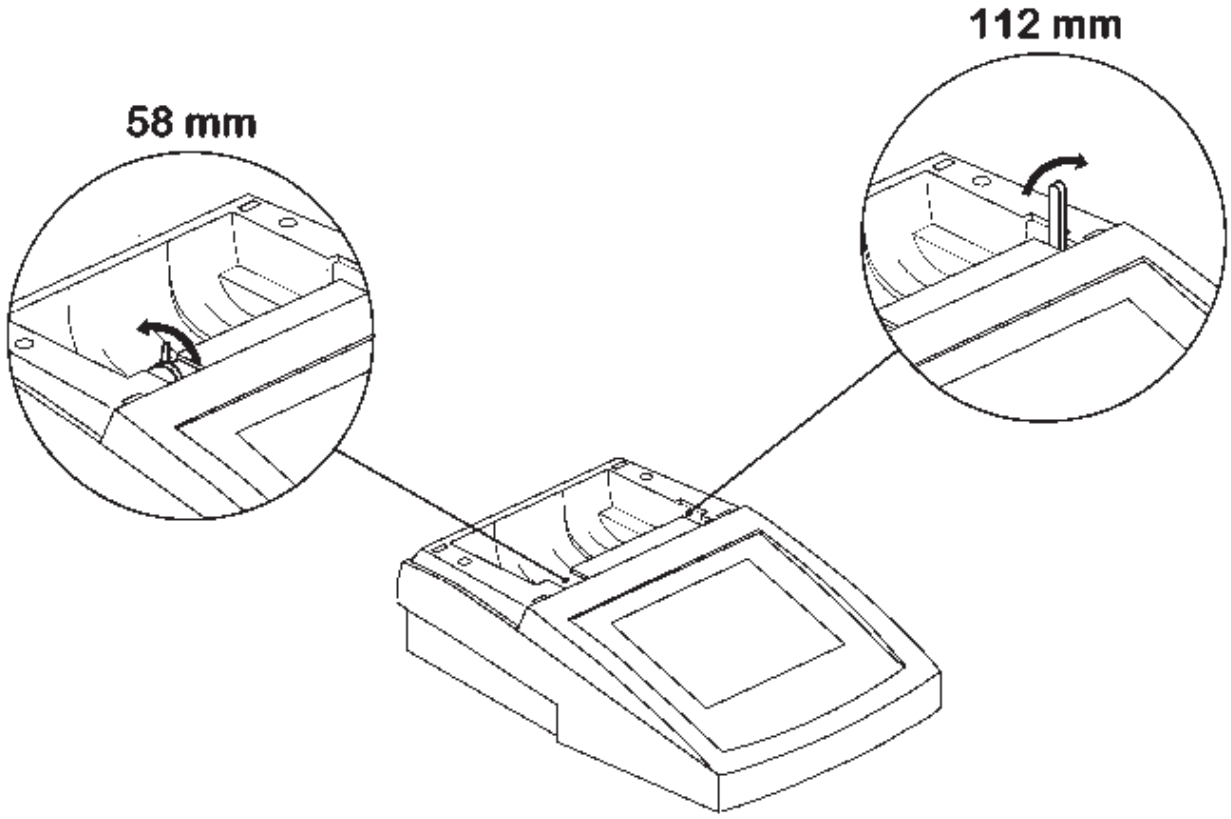
The B, C and D models work with thermosensitive paper of 111 mm wide and model A with thermosensitive paper of 58 mm wide. In this manual all the reports are made with wider paper.

To load the paper in the printer, follow the next detailed instructions.

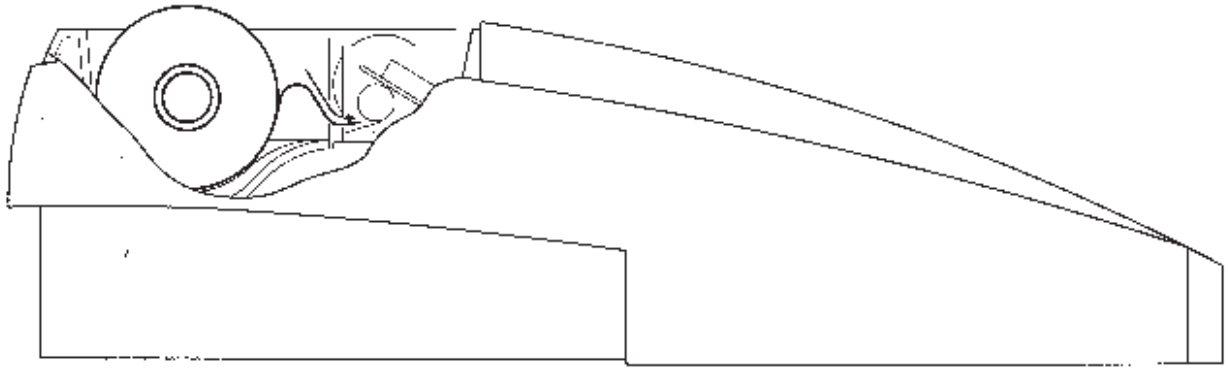
1st Open the paper cover



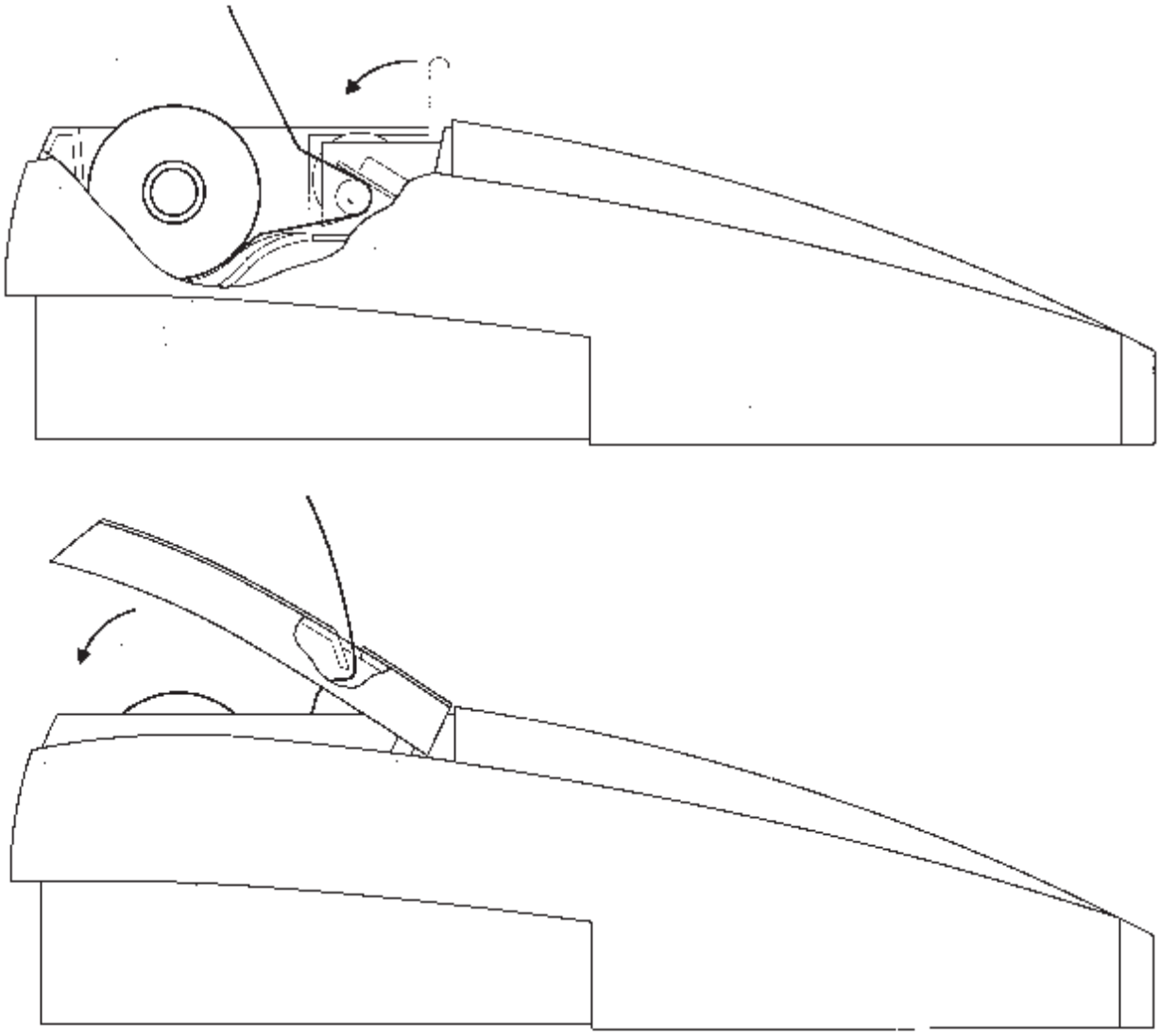
2nd Lift the lever that unlocks the pull cylinder.



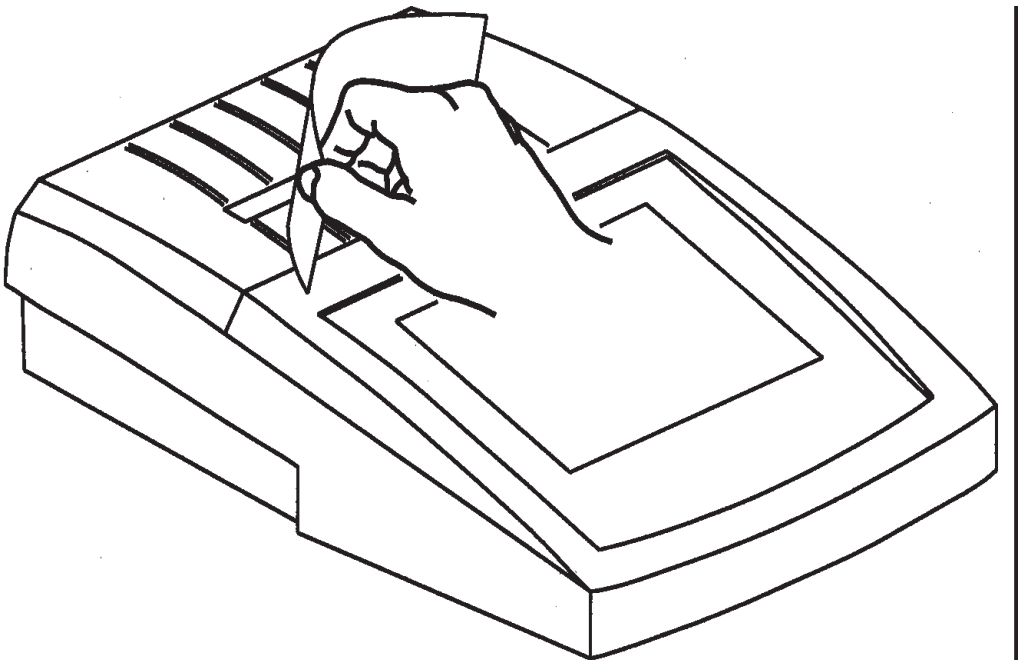
3rd Put the paper roll, as shown in the picture
4th Align the paper with the printer inlet and press F5 to feed the paper.



5th Take out some centimetres of paper, put down the header lever and close the cover , passing the paper through the slot.



6th Press F1 to go back to previous screen.
The paper cut is made pulling it forwards, as shown in the picture.



External printer can be connected to all the models (standard or optionally) if the external printer has been selected previously in the Configuration option. In this case, follow the instructions of the corresponding printer.

1.6. TREE OF FUNCTIONS OF THE SPIROMETER

For a better understanding of the structure of the spirometer DATOSPIR-110/120, the spirometer functions tree is presented. This structure corresponds to the most complete model with all the available options.

From the Main Menu, we can enter, depending to the included options, to:

DATABASE PROGRAM
CONFIGURATION PROGRAM
CALIBRATION PROGRAM
MAINTENANCE PROGRAM
SPIROMETRY PROGRAM
PULSE OXIMETRY PROGRAM
MAXIMALRESPIRATORY PRESSURES PROGRAM

It also includes a **COMMUNICATIONS SYSTEM** that allows the transfer of bi-directional information between the computer and the spirometer.

1.6.1. DATABASE PROGRAM

- **Summarised display of stored tests**
  - Printing and display of a test
  - Deleting a test
- **Search for patient code**
- **Summarised printing of the stored tests**
- **Deleting of all the stored tests**

1.6.2. CONFIGURATION PROGRAM

- **Configuration Pattern**
  - Restores the configuration
  - Saves the configuration
- **Common configuration**
  - Language of work
  - Insertion of a header in the report
  - Selection of printer type
    - Internal
    - External type HPCL
    - External type IBM Graphics
  - Patient code and others
    - Numeric
    - Alphanumeric
- **Spirometry Configuration**
  - Reference parameters
  - Observed parameters

FVC
VC
MVV

Graphic selection

Store graphics in the database
Print graphic Flow / Volume of FVC
Print graphic Volume/Time of FVC
Print graphic Volume/Time of VC
Print graphic Volume/Time of MVV

Print graphic Dose /Response in Bronchoconstriction
Selection of diagnosis
Mode of comparison in POSTbronchodilatation

% POND between PRE and POST
% Between REF and POST
% Between PRE and POST
Difference between PRE and POST

Selection of intervals, doses etc. in Bronchoconstriction
Other options

Printing of Nonconformity warnings of the manoeuvres with the ATS/ERS criteria
Incorrect start of the manoeuvre
Incorrect end of the manoeuvre
Incorrect time of the manoeuvre
Date of the last calibration
Selection of paediatric Incentive level

. Configuration of Pulse oximetry SpO2
. Configuration of Maximal Respiratory Pressures PIM-PEM

1.6.3. CALIBRATION PROGRAM

. Calibration with syringe
. Report of last calibrations

1.6.4. MAINTENANCE PROGRAM

. Selection of warnings

Period between calibrations
Period between maintenance

. Adjustment of LCD screen contrast (Liquid Crystal Display)
. Hardware check up
. Others

It informs of the Program Update password and allows initialising the system. Once the system is initialised, the user must select the model of the internal printer installed in the device.

With the introduction of some keywords the following options can be configured in this menu.

100 Permits the modification of parameters alfa, beta and pulse number.

101 Activates the plotting of VC maneouvre with positive espiration.

102 Activates the plotting of VC maneouvre with negative espiration.

. Check up with pattern curves
- FVC
- VC
- MVV

. Adjustment of printer contrast

1.6.5. SPIROMETRY PROGRAM

. Forced Vital Capacity test “FVC”
- Test data
  - Patient
    - Code
    - Name and surname
    - Age, height, weight and sex
    - Smoker index
    - Ethnic Factor
  - Environment
    - Temperature
    - Pressure
    - Humidity
- Start of the spirometric manoeuvre
- Presentation of the graphic
  - Flow/Volume (only in FVC)
  - Volume/Time
  - Paediatric incentive (only in FVC)
- Selection of manoeuvres
- Selection of the best manoeuvre
- Selected manoeuvre data
  - Memory for five manoeuvres
  - Deleting of a manoeuvre
  - Diagnosis
  - Store test for Postbronchodilatation
  - Store test in DataBase
  - Test printing

. Slow Vital Capacity test “VC”
- Similar to FVC

. Maximal Voluntary Ventilation test “MVV”
- Similar to FVC

. POSTbronchodilatation test “POST”
- Similar to FVC

. Bronchoconstriction test

- Test data
  - Patient
  - Environment
  - Time between doses
  - Type of medicine and dose
- Test method
  - Abbreviated
  - Normal or continuous
- Chronometer for time control
- Start of spirometric manoeuvre
- Graphic display
  - Flow/Volume
  - Volume/Time
  - Dose/Response
- Select manoeuvres
- Select best manoeuvre
- Test summary
- Store test in database
- Test printing

. Print a general report of tests performed to a patient

1.6.6. PULSE OXIMETRY PROGRAM

(See the Annex: PULSE OXIMETRY, if this option is included)

1.6.7. MAXIMAL RESPIRATORY PRESSURES PROGRAM

(See the Annex: MAXIMAL RESPIRATORY PRESSURES, if this option is included)

1.6.8. COMMUNICATIONS SYSTEM

. Transfer of patients tests

. Transfer of device check data

- Hardware check up
- Software check up
- Device configuration
- Calibrations record

. Software updating

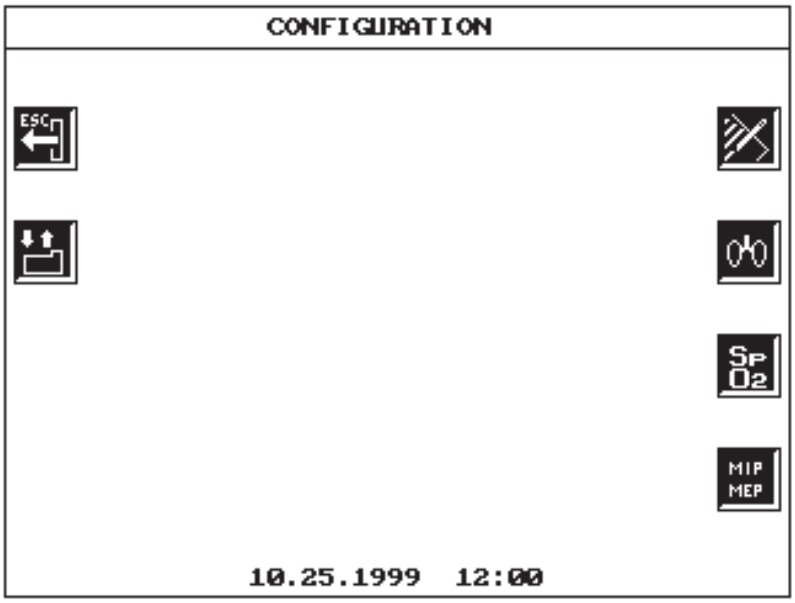
. Export of tests to other management systems

1.7. DEVICE CONFIGURATION

The multiple variety of options included in the spirometer **DATOSPIR-110/120** recommends that each user configures it according to his needs.

The different options in the Configuration Program will be detailed in point 1.6.2.

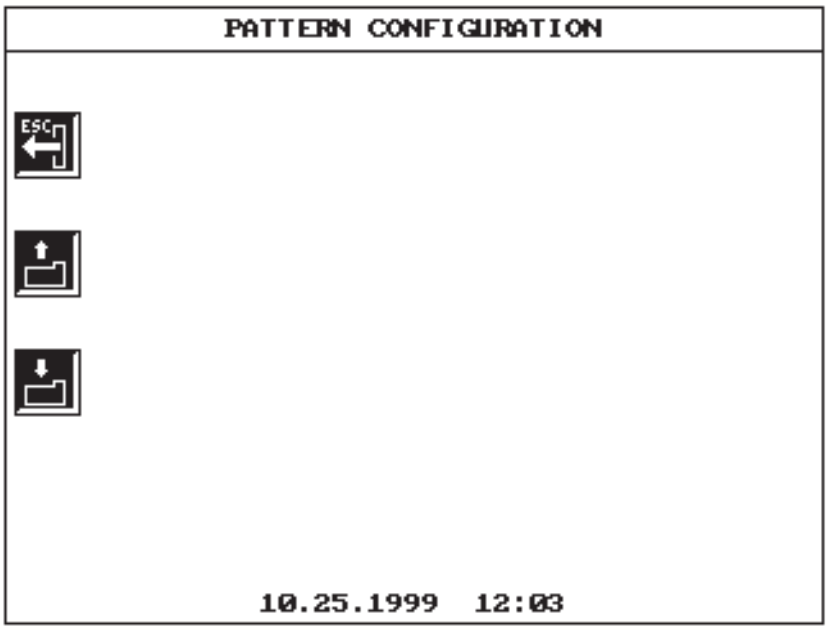
To enter this program, press key F2 in the Main Menu



F1 ESC, escapes from this screen and returns to the previous
F2 Pattern Setup
F5 Common Configuration
F6 Spirometry Configuration
F7 Pulse oximetry Configuration
F8 Configuration of Maximal Respiratory Pressures

1.7.1. PATTERN CONFIGURATION

This option consists of the memorisation of a status defined by the user of the configuration program in order to restore it at any moment global and automatically. This option allows restoring the configuration if it has been modified by any voluntary or involuntary circumstance. In general, this set-up is the most commonly used.



F2 Restores the Pattern Set-up
F3 Records the Pattern Set-up

To record the pattern Set-up, follow these instructions:

1st Configure each option:
Common Configuration
Spirometry Configuration
Pulse oximetry Configuration
Maximal Respiratory Pressures Configuration,
as detailed below.

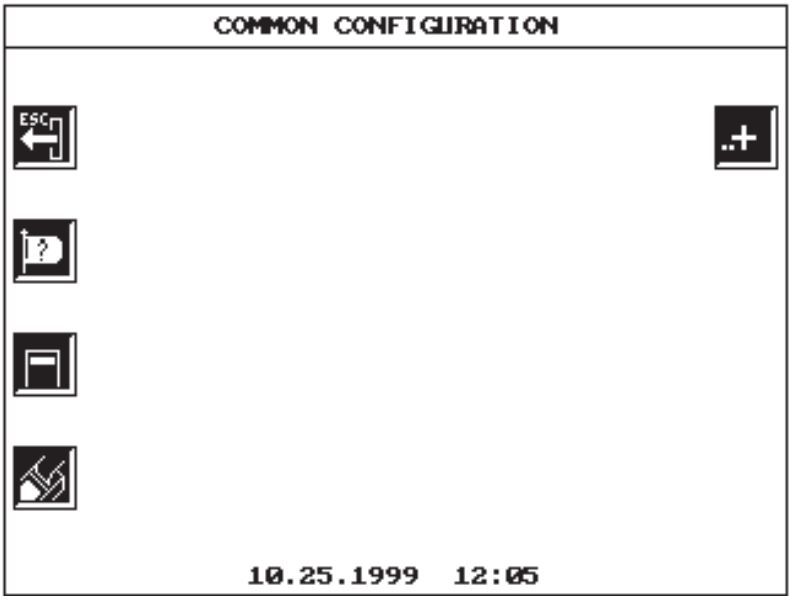
2nd Return to the Pattern Set-up and press key F3

3rd From this moment your Pattern Set-up is memorised.

If you need to modify any configuration option during a test performance, you can enter manually and modify it. The Pattern Set-up can be restored at any moment.

1.7.2. COMMON CONFIGURATION

In this option you can configure some common sub-options for any test available in the **DATOSPIR-110/120**.



F2 Selection of language
F3 Insertion of a header in the report
It enables to insert two lines of header with a maximum of 33 characters/ line.
Here you can write the name of the centre, doctor, etc. and it will appear in each report.
F4 Selection of printer type
F5 Code for patient and others
Select among numeric and alphanumeric code.
It is recommended the numeric code, as the second is slower to enter.

1.7.3. SPIROMETRY CONFIGURATION

In this option you can configurate those suboptions specific for the spirometric tests.

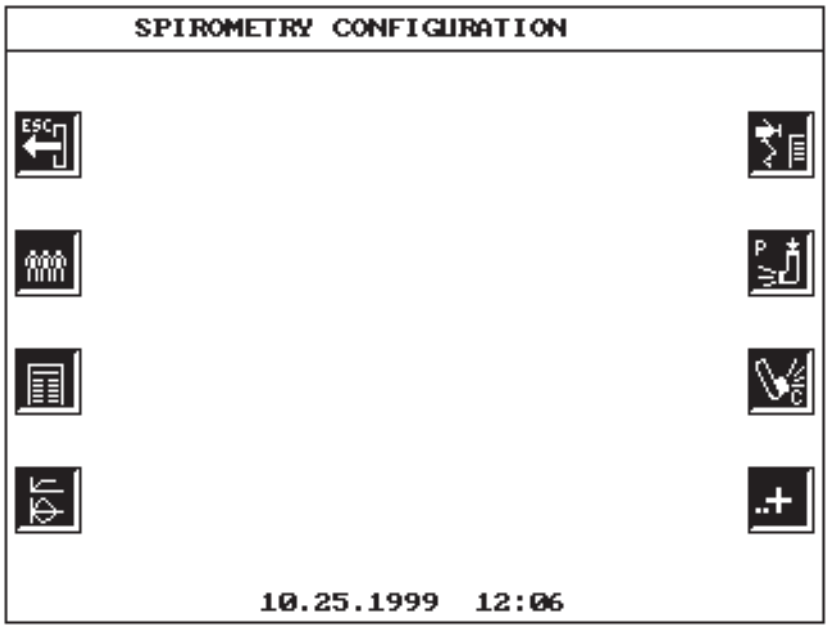
F2 Reference Parameters
Enables to select among several
Selects for children and adults
Prioritizes the range of age selected for adults if a different table for children is selected.
Extrapolates the values for the ages out of the range of the selected tables.
F3 Observed Parameters
Enables to select the preferred observed or measured parameters
F4 Selection of Graphics
F5 Selection of diagnosis according to

Miller's quadrant
Snider, Kory & Lyons algorithm

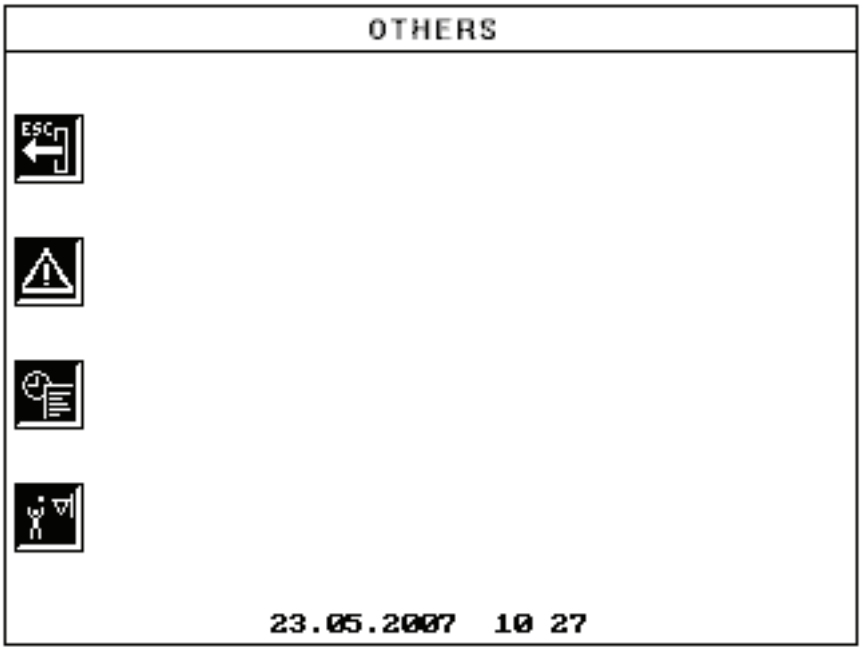
F6 Mode of comparison between PREbroncho and POSTbroncho
- %P Weighted average between PRE and POST
- % Percentage between REF and POST
- % Percentage between PRE and POST
- Dif Difference between PRE and POST

F7 Bronchoconstriction
Some aspects like mode, drug, time, etc.

F8 Others options



1.7.4. OTHERS OPTIONS



F2: The non applicance of the ATS/ERS criteria of the Start, End and/or Time of the manoeuvre, as well as the date of the last calibration, can be printed or not in the report.

EX Incorrect Start of the manoeuvre
ET Incorrect End of the manoeuvre
TT Incorrect Time of the manoeuvre

F3: Time Audit:
Show the time when the manoeuvre was performed. It's shown in the first line of the parameters list, both in the screen and in the report.

F4: The user can adjust the level of the incentive as he wants, according to:
First manoeuvre, % of the FVC value, according to the Reference
Rest of manoeuvres, % of the FVC value, according to the Best.

1.7.5. PULSE OXIMETRY CONFIGURATION

(According to Annex: PULSE OXIMETRY, if this option is included)

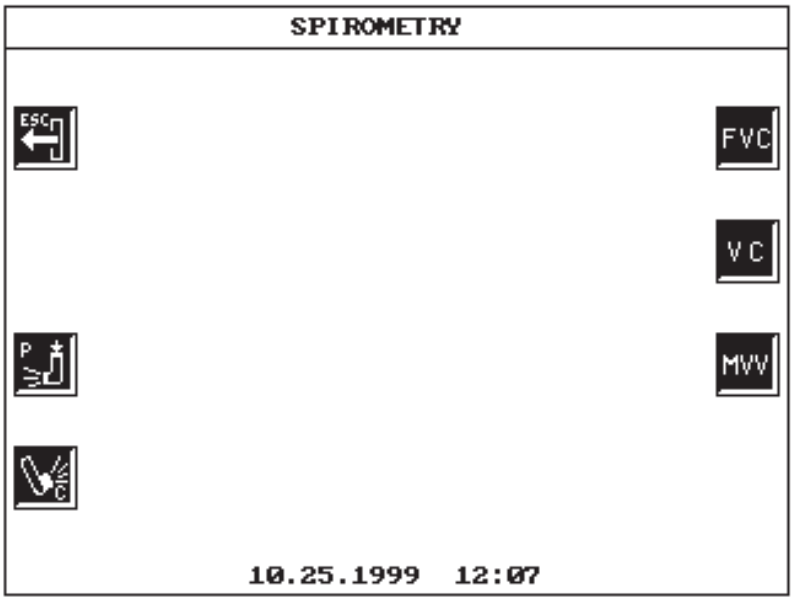
1.7.6. MAXIMAL RESPIRATORY PRESSURES CONFIGURATION

(According to Annex: MAXIMAL RESPIRATORY PRESSURES, if this option is included)

1.8. PROCEDURE FOR FORCED VITAL CAPACITY TEST “FVC”

The procedures to be used in order to perform the **Forced Vital Capacity tests “FVC”, slow Vital Capacity “VC” and Maximal Voluntary Ventilation “MVV”** are very similar. Therefore, a detailed description will be done only in this point.

From the **Main Menu** screen, press key F5

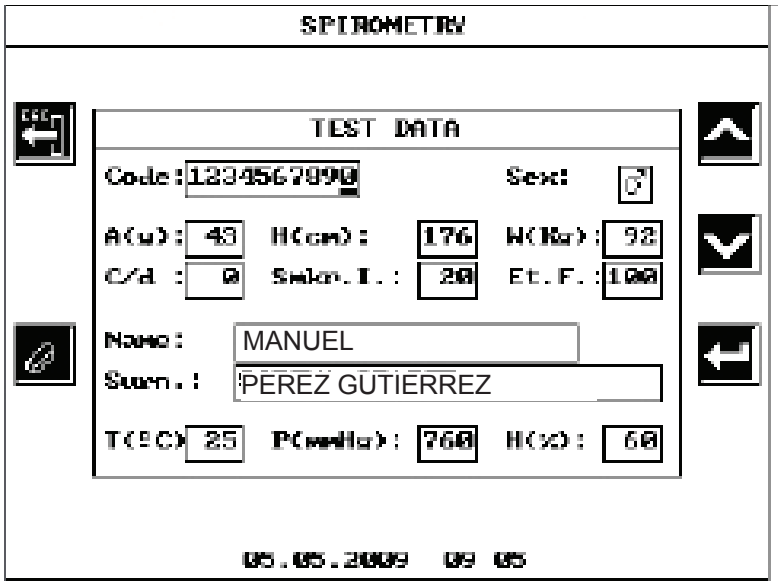


F2 Input of a new patient, if it appears
F3 Test of **POSTbronchodilatation**
F4 Test of **Bronchoconstriction** or Bronchial Provocation
F5 **Forced Vital Capacity** Test
F6 **Slow Vital Capacity** Test
F7 **Maximal Voluntary Ventilation** test
F8 **General report**, if it appears

The general report displays the FVC, VC MVV tests altogether, performed to the same patient.

Press F5

1.8.1. INPUT OF PATIENT AND ENVIRONMENTAL PARAMETERS



Fill in the parameters in according to:

F2	Enables to insert a character, if it appears
F3	Deletes a character
F4 and F8	Moves the cursor to the left or right inside the same field (for text fields like Name and Surn.)
F8	Shows the screen where to introduce the factor when it is a disposable
F5 and F6	Returns the cursor to the previous field or advances it to the next one
F7	Validates the entered data and goes to the next screen

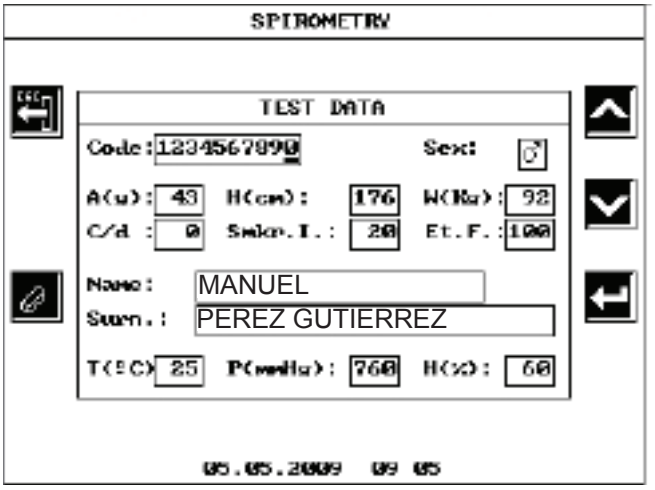
The alphanumeric characters are entered through the keyboard of the device. Each key has different alphanumeric characters associated (for example, key “3” has also D, E and F). With the first hit in an alphanumeric field, the “3” is presented, with the second one, the “D”, with the third one, the “E” and with the fourth one the F”, provided that the time between hit and hit is lower than 0.6 seconds.
The cursor goes to the next character when pressing a different key or after 0.6 seconds from the last hit. This method is similar to the one used in the celular telephones.
It is only possible to enter characters in capital letters.

The available characters are:

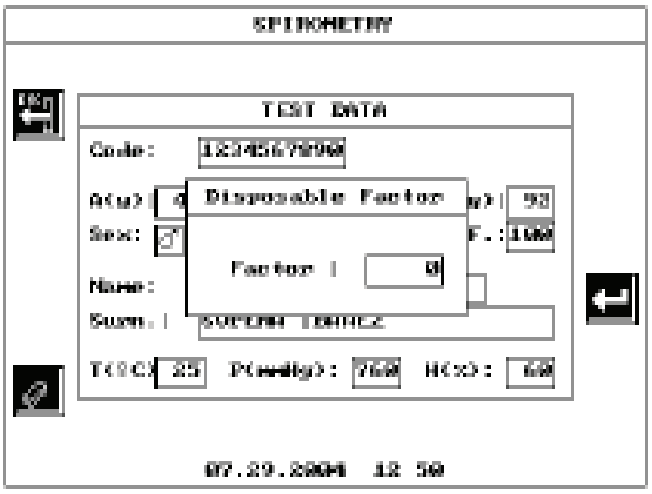
		1	**2**	**3**	**4**	**hits**
Key	**1**	1	!		.	
“	**2**	2	A	B	C	

“	**3**	3	D	E	F
“	**4**	4	G	H	I
“	**5**	5	J	K	L
“	**6**	6	M	N	Ñ
“	**7**	7	O	P	Q
“	**8**	8	R	S	T
“	**9**	9	U	V	W
“	**0**	0	X	Y	Z

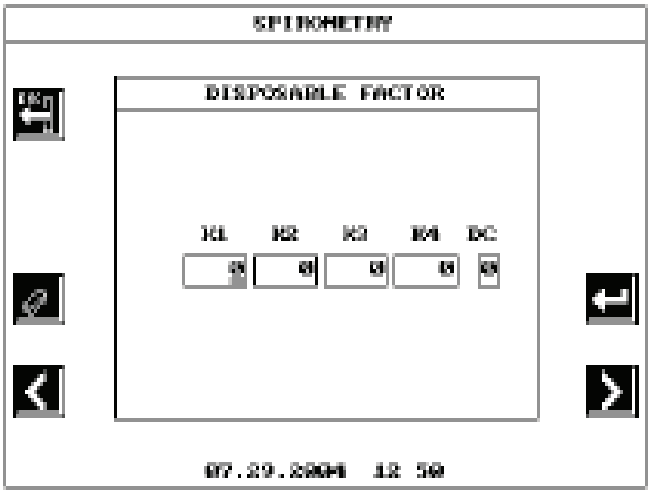
The third hit on the key “1” corresponds to the blank space.



For the disposable, the display appears like this:
Si se pulsa F8 se accederá a la pantalla que permite la intrudcción del Código Transductor (siempre que el Transductor sea un Desechable). El número a introducir en esa pantalla debe coincidir por el indicado en la etiqueta de cada bolsa.



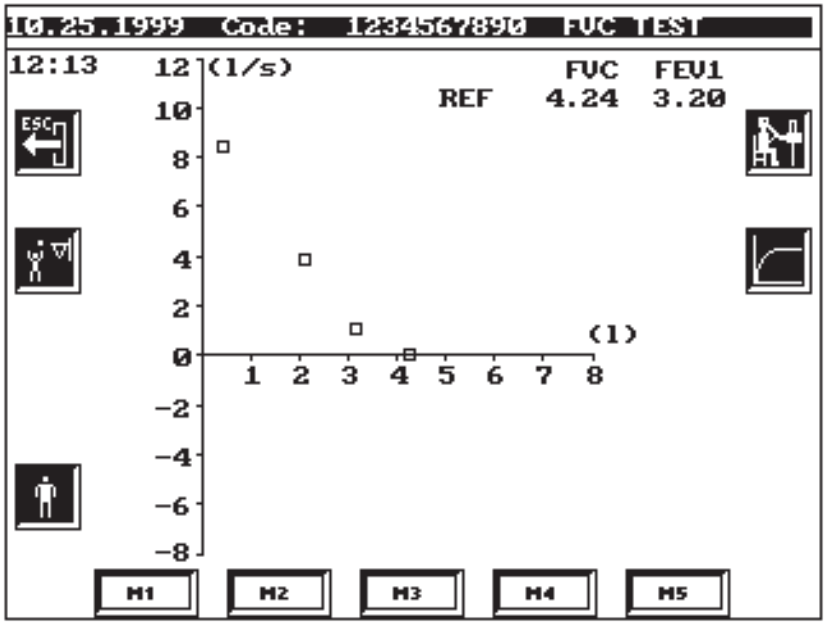
If the lot is not already introduced, the next screen appears to be able to write down the «K's»:



The meaning of each field is as follows:
Code: Field of 10 numeric or alphanumeric characters, according to the configured option
Age: Number corresponding to the years between 4 and 100, both inclusive
Weight: Idem for the weight in Kg. between 15 and 200
Height: Idem for the height in cm between 50 and 230
Sex: Through the key "1" for FEMALE and the key "2" for MALE
C/d : Cigarettes/day. Between 0 and 100.
Smoker I.: Smoker Index between 0 and 200 cigarettes day multiplied by the number of years.
This index is the same as the number of cigarettes smoked per day divided by 20 and multiplied by the number of years as a smoker.
(Cigarettes day x years as a smoker/ 20)
Et. F.: Ethnic factor between 80 and 120%. The ethnic factor is used in those places which do not have own reference parameters and use some existing and corrected in certain percentage.
This factor **MUST BE IN 100 IF IT IS NOT USED** and it can only be modified hrough the Configuration Program.
Name: Alphanumeric field of 20 characters, it can be omitted
Surname: Alphanumeric field of 25 characters, it can be omitted

The environmental parameters are received by the **DATOSPIR-110/120** automatically if the **ELECTRONIC WEATHER STATION** is available, which is inserted in the connector no. 15 of the back pannel. If this option is not available, the parameters are entered manually from the environmental data available of the room where the test is performed.
T (ºC) Room Temperature between 10 and 40 ºC
P(mmHg) Environmental pressure between 430 and 800 mmHg.
(from 4500 to -400 metres high approx.)
H(%) Relative humidity between 0 and 100%
Once the data have been entered correctly, press key F7.

1.8.2. INPUT OF FORCED VITAL CAPACITY TESTS “FVC”



F2 Activates the incentive mode
F4 Enables to modify the Patient and environmental data
F5 Starts the manoeuvre
F6 Changes the type of graphic, Flow/Volume or Volume/Time
F8 Key to introduce the Disposable Factor (only if the disposable transducer is connected)

It is convenient that the user who performs the forced spirometry tests, knows the usual procedure required, so that the patient does the test correctly. Otherwise, it is advisable to check some information regarding this matter.

In the performance of this spirometry, take into account the following steps:

1st Connect the transducer in the connector no. 7. The device detects automatically the type of transducer to which it is connected

Neumotachometer type Fleisch
Transducer type turbine
Transducer type disposable

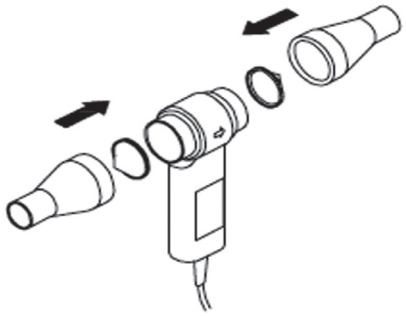
When the transducer is a disposable, the calibration factor introduced in the unit will appear above the curve’s zone.
Moreover, the first time getting in the testing screen, F8 key will be activated to be able to change the factor.

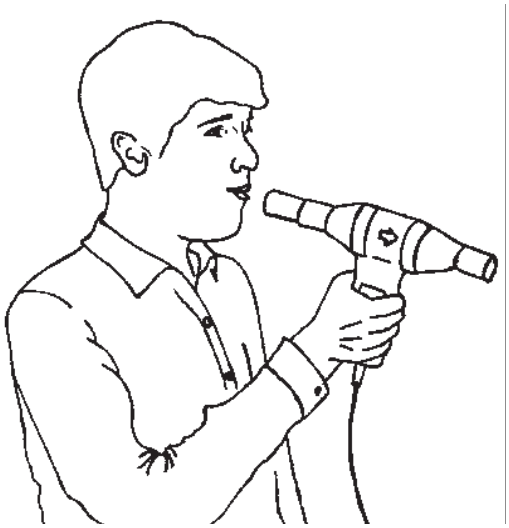
For all the tests performed in the **DATOSPIR-110/120**, the neumotachometer type Fleisch must by at 37 ºC, except during the device calibration , which must be at room temperature.
If the neumotachometer is not working at temperature (37 ºC), a label appears,

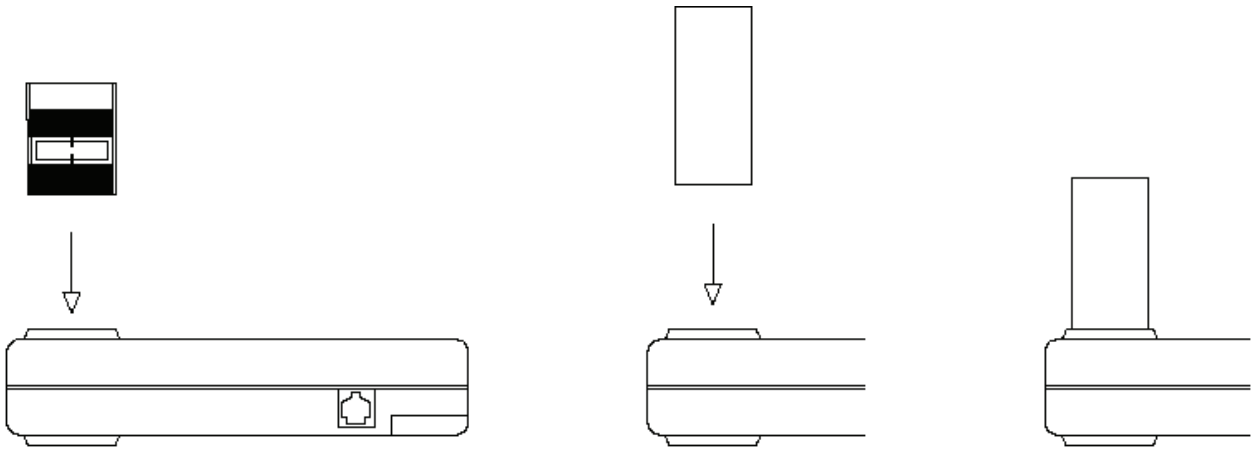
warning about this circumstance. The heater time is 5 minutes approx. from the moment of entering the Spirometry Program.

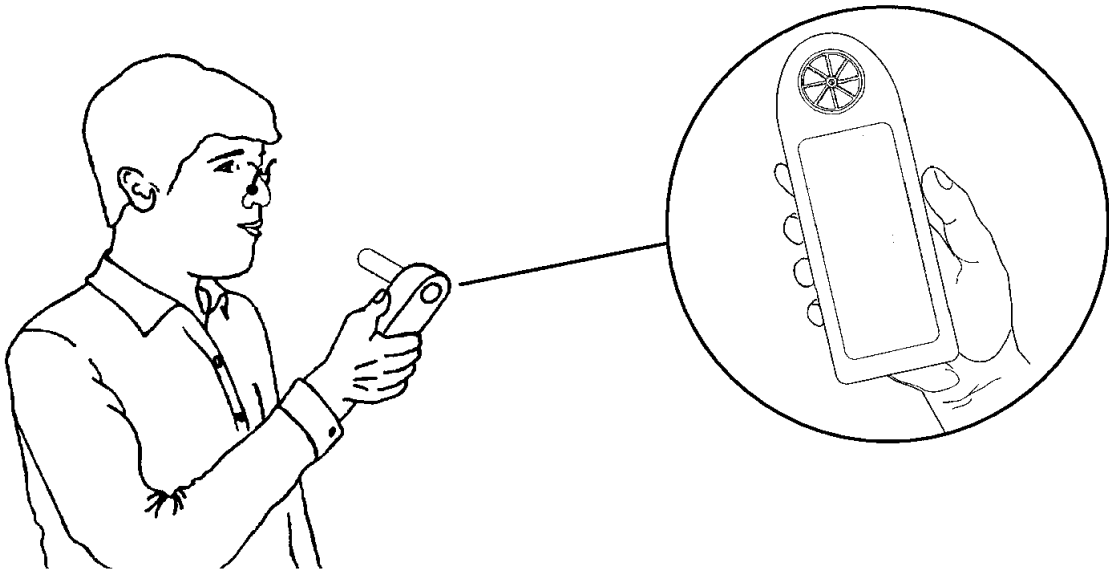
The heater avoids the condensation inside and performs the measuring in **BTPS conditions. (Body Temperature and Pressure and Saturated with water vapour)**, this is, in the conditions of the air in the lungs.
The transducers type turbine or disposable, are not heated but the spirometric data are presented in BTPS conditions.

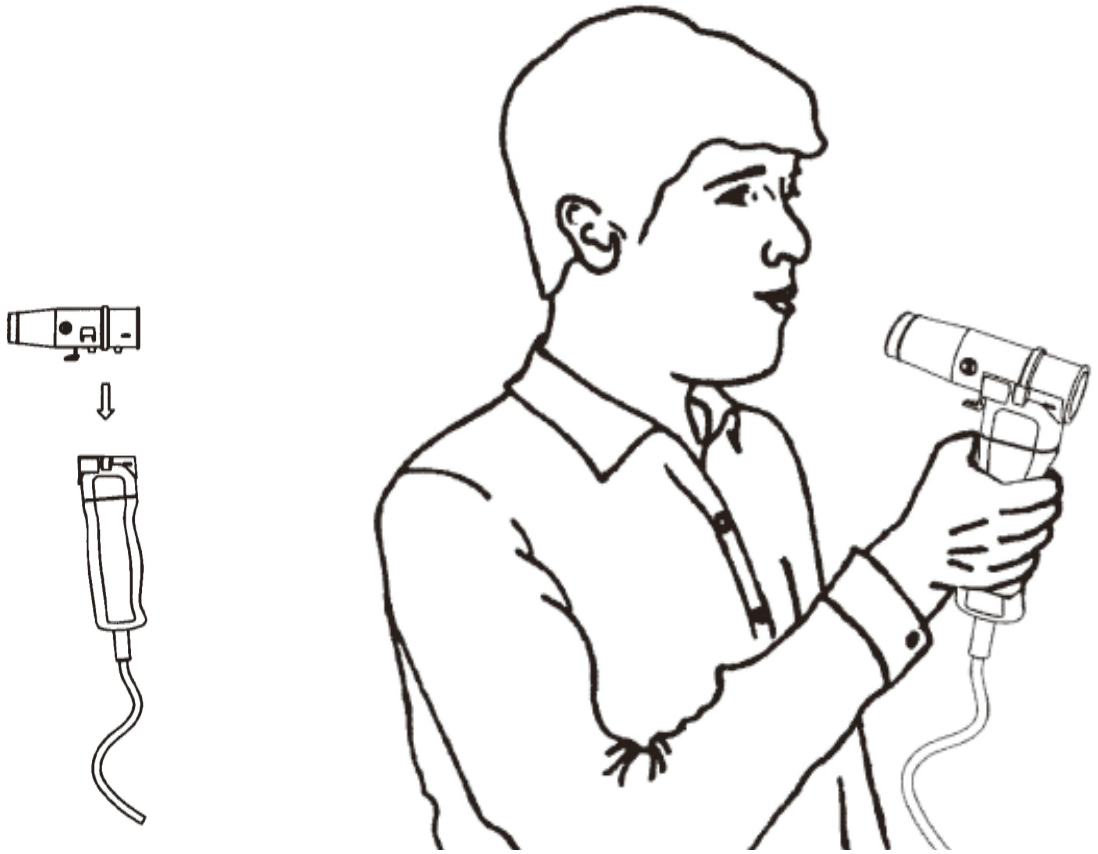
2nd Verify that the neumotachometer or transducer is assembled as detailed in the following pictures:











3rd Train the patient in the test performance, because his collaboration is essential for the correct realization. Put him the nose clip.

Explain to the patient to hold the pneumotachometer quietly to start blowing. The pneumotachometer should be hold in the same position until the end of menoeuvre.

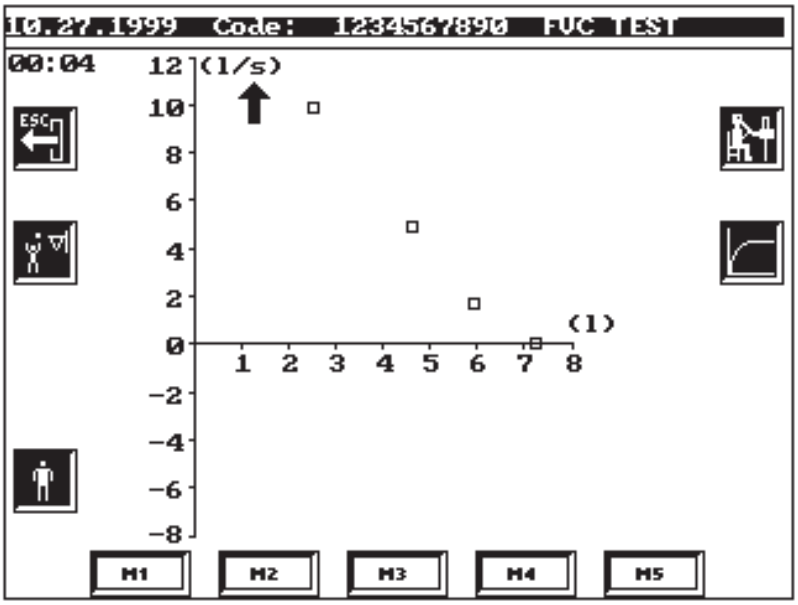
Check point **4. - SPIROMETRY TECHNIQUE**.

The patient can make the spirometric manoeuvre in two different methods:

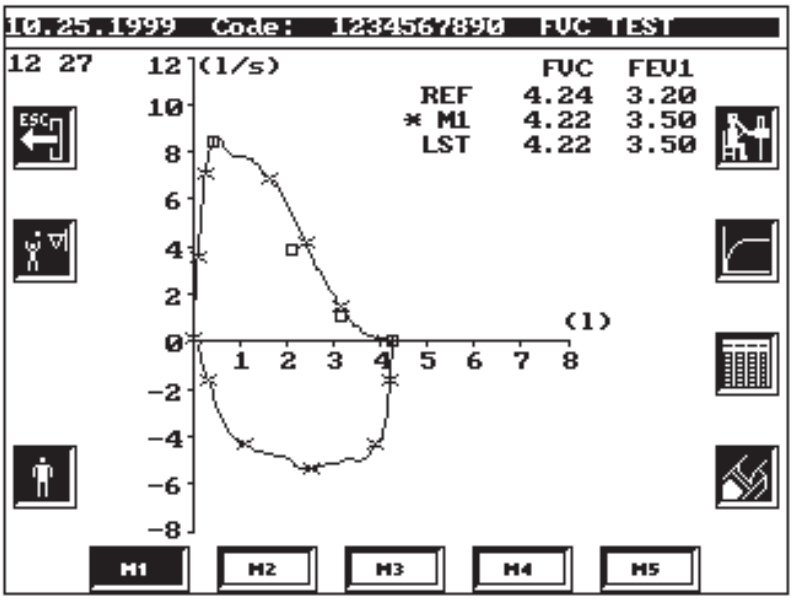
- The first method consists of starting the manoeuvre over the neumotachometer or transducer with the FORCED EXPIRATION followed by the FORCED
INSPIRATION, if necessary.
- The second method consists of the patient breathing normally through the neumotachometer or transducer. When the operator indicates, fill the lungs completely and then start the FORCED EXPIRATION followed by the FORCED INSPIRATION, if necessary.

Note: if an FVC-loop has to be recorded and the FORCED INSPIRATION is not shown on the screen, please verify that there is some inspiratory parameter selected in the Spirometry Configuration menu (see section 1.7.3).

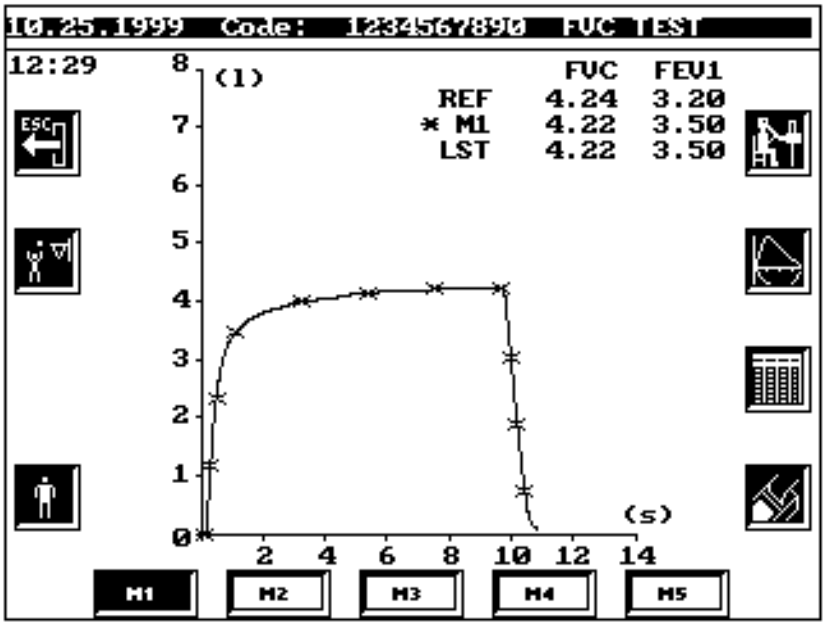
4th Press key F5 and keep the neumotachometer or transducer quiet until an intermittent arrow appears on the screen.



From that moment, start the spirometric manoeuvre.



Through key F6 the graphic presentation mode changes



When the device has detected the end of the expiratory manoeuvre according to ATS/ERS criteria (volume accumulated during the last second lower than 0.025 litres), warns with an acoustic signal to start the inspiratory cycle or finish the manoeuvre.

5th The previous screen presents or gives access to the following information:
- Date, patient code and type of test
- Warnings of Nonconformity with the ATS/ERS criteria

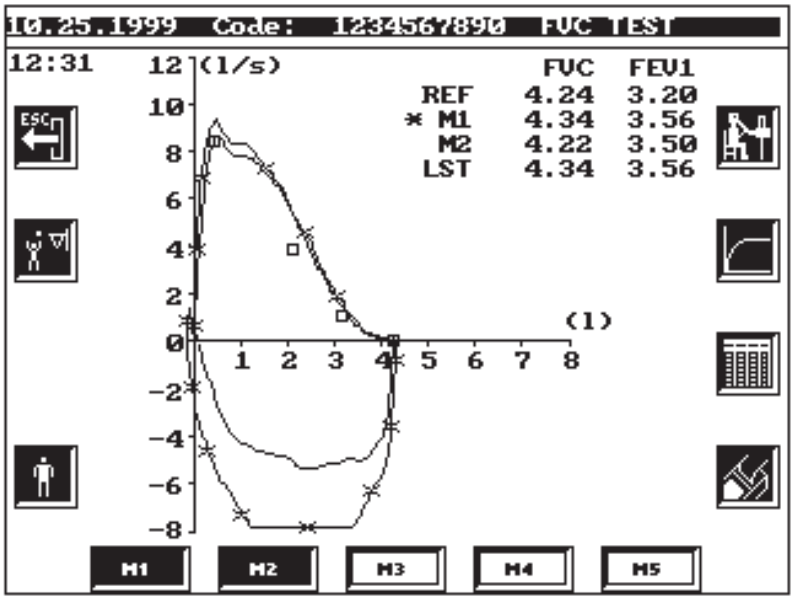
ET - Indicates that spiration has not completed satisfactorily, as the variation on volume in the last second of the manoeuvre was above 25 ml, or the manoeuvre has lasted less than 6 seconds (in patients aged over 10 and more) or less than 3 seconds (in patients aged 10 or less).

EX - Indicates that the start of expiration was not satisfactory, as the extrapolated volume is above 5% of the FVC or 0.15 litres. The ATS/ERS recommends it be less than 5% the FVC or 0.15 litres, whichever is highest.
- Time in seconds of the expiratory plus the inspiratory manoeuvre.
- Graphic in mode Flow/Volume or Volume/Time
- FVC and FEV1 values of Reference (REF) and the Observed values in each manoeuvre (Mx)
- ACT (current) corresponds to the last entered manoeuvre.
- In mode F/V some small squares appear, which correspond to the theoretical values of FVC, MEF25%, MEF50% and MEF75%, if there are references for them.
- The number of stored manoeuvres, in this case only one, M1
- The icons give access to

F2 Activates the paediatric incentive
F5 Initialize a new manoeuvre
F6 Changes the type of graphic F/V or V/T

F7 Presents the data of the best manoeuvre
F8 Prints the report of the best manoeuvre

6th Perform new spirometric manoeuvres



- The new graphic superposes to compare it with the best (M1) of the stored manoeuvres

The device **DATOSPIR-110/120**, according to the **FVC+FEV1 criteria of larger addition**, stores automatically and puts in order the five best manoeuvres in M1 to M5, being the **BEST the placed in M1** and the **WORST the placed in M5**. It also takes into account the number of Nonconformity warnings (EX, FP, TP), being the worse the more warnings it displays.

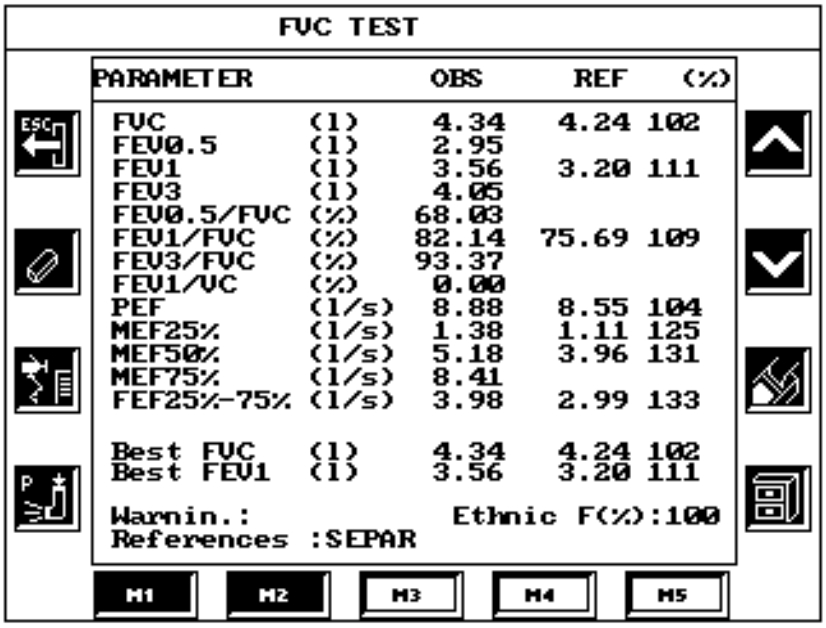
- The last entered manoeuvre keeps blinking and corresponds to the values ACT (current). If more than five manoeuvres have been entered, and no manoeuvre blinks, it means that the last input is worse than the five stored manoeuvres, and then it will delete it.
- If three or more manoeuvres have been performed and the labels **FVC and/ or FEV1** blink, they warn that the **reproducibility criteria** is met, according to the ATS/ERS for one or for both parameters. This criteria indicates that the best two observed values of FVC and the two best values of FEV1 must not differ in more than 0.2 litres and, in this case, the test can be considered as acceptable.

The different standards recommend performing, at least, three satisfactory manoeuvres where the reproducibility criteria is met. Do not surpass the eight, as this could mean the tiredness of the patient.

NOTE: Remember that going back in the menu without losing the available information up to that moment is possible with the backspace F1 “ESC”, except if we change the patient entering a new code or in any other situation. Anyway, it is indicated on the screen.

1.8.3. DISPLAY OF THE RESULTS

Press key F7



When entering this option, the results for the best manoeuvre M1are presented.
In order to see the values for another manoeuvre, press the corresponding key, M1 to M5

- The screen presents Reference, Observed values and % between both selected in the Configuration Program.
- It also presents the best values for FVC and FEV, which can correspond to different manoeuvres.
- Values of Reference used
- Ethnic factor (if it is not used, it must be 100)
- Nonconformity warnings with the ATS/ERS criteria for each manoeuvre
- The icons give access to:

F2	Deletes the selected manoeuvre
F3	Presents the diagnosis based in the selected manoeuvre
F4	Stores the selected manoeuvre in order to compare it with the test POSTBRONCODILATION, if this is going to be performed
F5, F6	Displays the rest of parameters, if they are selected
F7	Prints the report of the selected manoeuvre
F8	Stores the selected manoeuvre in the INTERNAL DATABASE

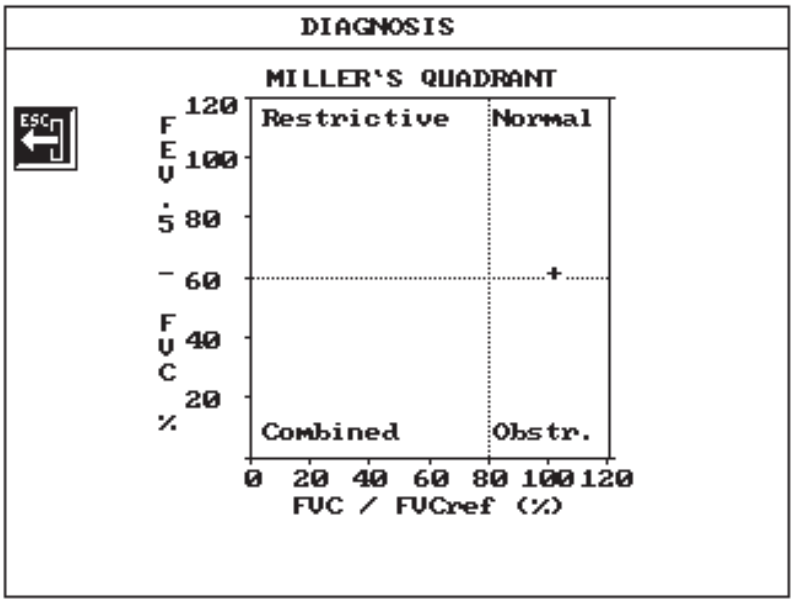
WARNING

As previously mentioned, the BEST manoeuvre is placed in M1. Therefore, in order to present the diagnosis, print the report or store the manoeuvre for the POSTbronchodilatation or for the Internal Data , the M1 must be used, except if the user prefers to use another one.

1.8.4. TYPE OF DIAGNOSIS

The spirometer **DATOSPIR-110/120** has two types of diagnosis to select in the Configuration Program.

A.- **Miller diagnosis**
Presents the following information **NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED,** according to the criteria of the following quadrant.



B.- Snider, Kory & Lyons diagnosis

It is based on the following criteria:

If FVC > 80% of FVC Reference
and FEV1 > 80% of FEV1 Reference

Values in the reference range. Normal Diagnosis

If FEV1/FVC% < Reference FEV1/FVC%
and FEV1 < 80% of FEV1 Reference

Ventilatory Alteration of Obstructive type

FEV1 < 80%	**Light**
FEV1 < 65%	**Moderate**
FEV1 < 50%	**Strong**
FEV1 < 35%	**Very strong**

If FEV1/FVC% > FEV1/FVC% Reference
and FVC < 80% of FVC Reference

Ventilatory alteration of No Obstructive type

FVC < 80%	**Light**
FVC < 65%	**Moderate**
FVC < 50%	**Strong**
FVC < 35%	**Very Strong**

If FEV1/FVC% > FEV1/FVC% Reference

and FVC > 80% of FVC Reference
A ventilatory alteration of mixed type is suspected

If FEV1/FVC% < FEV1/FVC% Reference
y FEV1 > 80% of FEV1 Reference
A ventilatory alteration of mixed type is suspected

If a POSTbronchodilatation test is performed
And the FEV1 POST is over 15 % to the FEV1 basal or PRE
There is a positive response to the bronchodilator drug

NOTE:
THE SPECIALIST ALWAYS MUST VALIDATE THE DIAGNOSIS AND THE RESULTS OF THE TEST.

1.8.5. PRINTING AND /OR MEMORISATION OF THE FVC TESTS

After performing at least one manoeuvre, any of these operations can be done:

A.- Printing of the results

Once the corresponding manoeuvres are performed, press F7 on the data screen or F8 on the graphic screen and the following display will appear

DR. JOHN SMITH
SAINT PETER HOSPITAL. PNEUMOLOGY

DATOSPIR 120 - SIBELMED

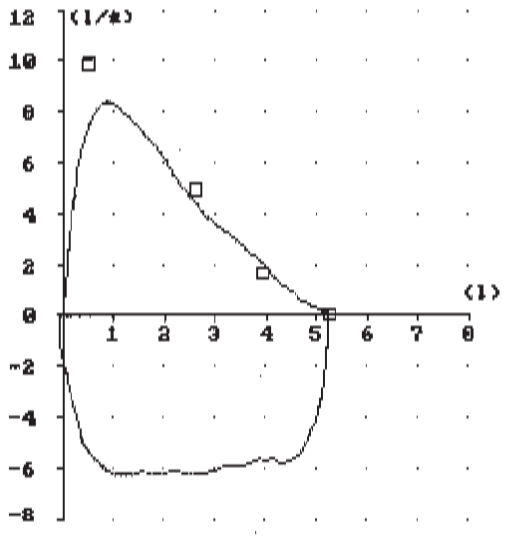
Code:	1234567890	Date: 30.10.1999	
Name:	CHARLES FORESTER		
Sex:	Male	Age(y):	43
Hght.(cm):	176	Wght(Kg):	92
Temp(ºC):	25	Humid.(%) :	75
Pres(mmHg):	760	Smk.I.:	20
References :	SEPAR	Ethnic F(%):	100
Motive:			
Procedence:			
Techn. :			
Transducer:	Fleisch		

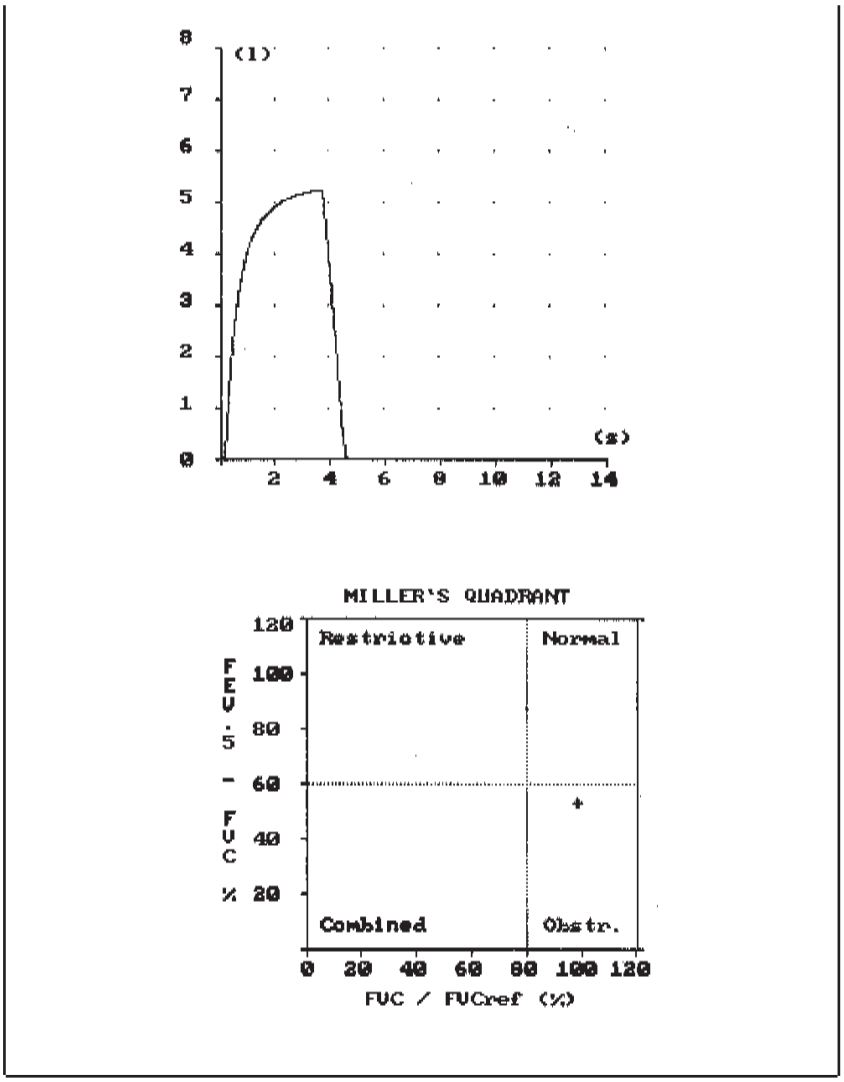
FVC REPORT MANOEUVRE N: 2/2

PARAMETER		OBS	REF	(%)
Best FVC	(l)	5.44	5.25	104
Best FEV1	(l)	4.44	4.04	110
FVC	(l)	5.24	5.25	100
FEV1	(l)	4.26	4.04	105
FEV1/FVC	(%)	81.20	77.40	105
PEF	(l/s)	8.26	9.96	83
MEF50%	(l/s)	4.33	4.99	87
FEF25%-75%	(l/s)	4.04	3.89	104
FET100%	(s)	3.89		
MEF50% / MIF50%		0.69	0.66	104
FEV1/PEF	(%)	8.58	6.64	129
MIF50%	(l/s)	6.30		
FIVC	(l)	5.34		

Comments : .....

.....





The report presents the parameters of the selected manoeuvre plus the best values for FVC and FEV1 among all the available manoeuvres.

The parameters, graphics, diagnosis and other information of the report can be adapted to the user´s needs through the Configuration Program.

Remember that a general report or a set of tests FVC, VC and MVV can also be made, as specified at the beginning of point 1.8.

B.- Memorisation of a test to compare it in POSTbronchodilatation mode

This option enables to store a test in PREbronchodilatation mode to compare it to the POSTbronchodilatation mode.

- Enter the data screen and select the manoeuvre to be memorised, usually M1. Next, press F4 to save it.

-If a test has been memorised incorrectly, select the correct one and proceed again. This new information will replace the previous one.

If it is a Disposable Transducer, when a PREbronchodilatation manoeuvre is stored, it stores also the calibration factor so it can be used later on the POSTbronchodilatation test if wanted so.

C.- Memorisation of a test in the Internal DataBase

This option stores the test in the Internal DataBase of the device to display it, print it and /or transfer it to a computer

- Proceed as in previous point but through key F8.

1.8.6. OTHER SPIROMETRIC TESTS TO THE SAME PATIENT

After performing the FVC test to a patient, it is possible to make the following spirometric test to the same patient:

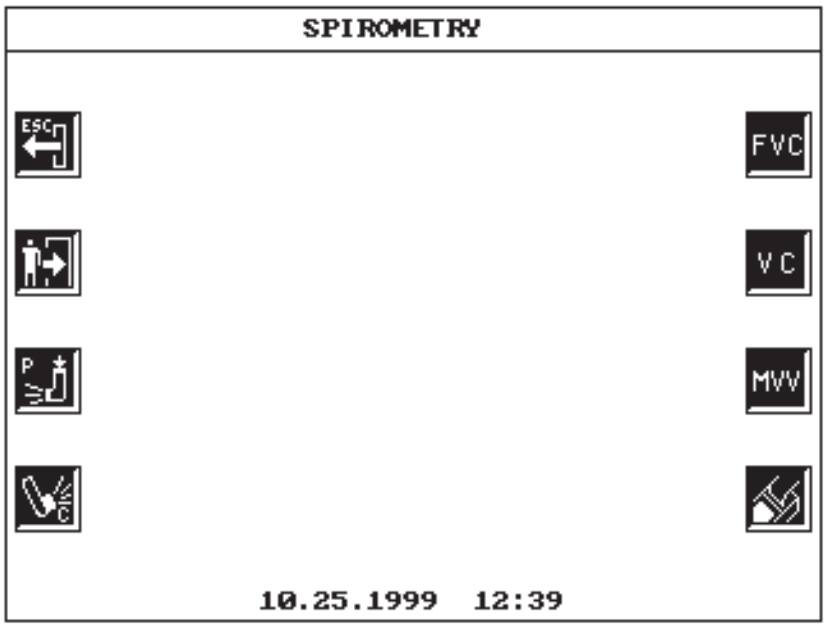
- A **VC** test
- A **MVV** test
- A **Postbronchodilatation** test
- A **Bronchoconstriction** test

It is also possible to:

- Print the general report of all the tests of the same patient
- Start the process of tests with other patient

The spirometer stores automatically the best manoeuvre for each test of FVC, VC MVV and /or POSTbronchodilatation, in order to print, if preferred, a general report with all the test before going to another patient.

Go back to the screen shown and select the option.



F2 New patient
F3 POSTbronchodilation test
F4 Bronchoconstriction or Bronquial Provocation
F5 Forced Vital Capacity test
F6 Slow Vital Capacity test
F7 Maximal Voluntary Ventilation test
F8 General report

1.8.7. CHANGE OF PATIENT

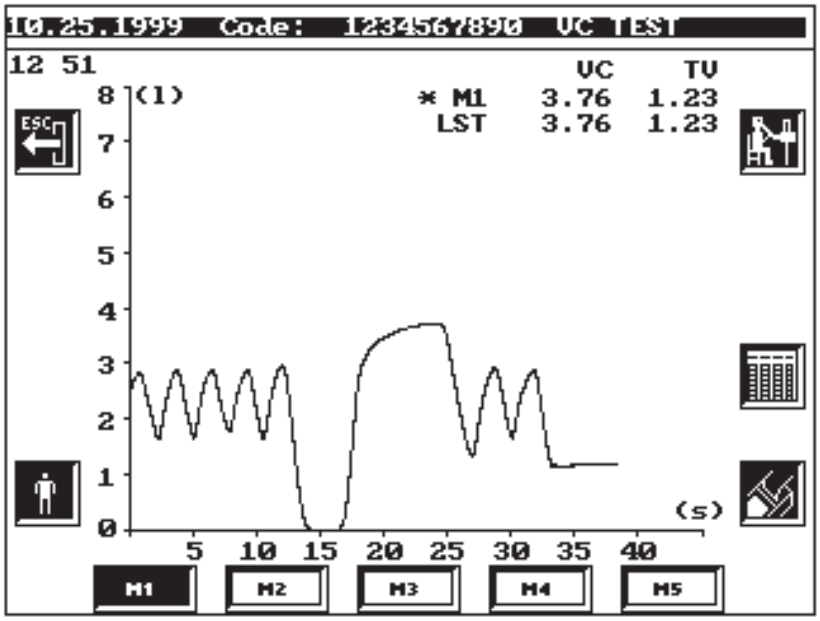
To change the patient, press key F2 on the previous screen and follow the instructions indicated in the point 1.8.1.

As mentioned above, when entering this option and a new patient code, the available information of the previous patient is deleted, except the information stored in the Internal DataBase, or the information stored to perform a Postbronchodilatation spirometry.

1.9. PROCEDURE FOR SLOW VITAL CAPACITY TEST "VC"

The procedure to perform the slow **Vital Capacity test "VC"** is similar to the one described in point **1.8. PROCEDURE FOR FORCED VITAL CAPACITY TEST "FVC"** with the following variations.

1st Enter the "VC" test and perform a manoeuvre



2nd The presentation of the axis is always made in VOLUME/TIME mode and the incentive is not available.

3rd The maximum time to perform the manoeuvre is 45 seconds. They are put in order beginning with the manoeuvre of higher VC.

4th To measure correctly the parameters ERV and TV, each manoeuvre must at least have four respiratory cycles at basal level.

5th The record of parameters and graphics is displayed next, according configuration. It is not allowed to superpose the manoeuvres in VC mode, as they will not give any complementary information.

DR. JOHN SMITH
SAINT PETER HOSPITAL. PNEUMOLOGY

DATOSPIR 120 - SIBELMED

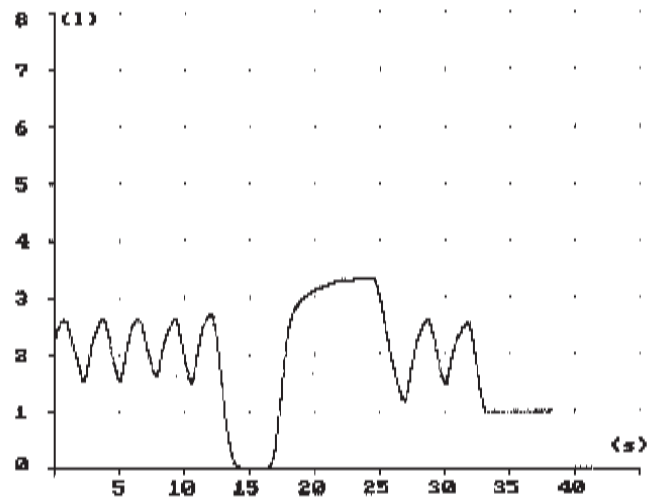
Code:	1234567890	Date:	30.10.1999
Name:	CHARLES FORESTER		
Sex:	Male	Age(y):	43
Hght.(cm):	176	Wght(Kg):	92
Temp(ºC):	25	Humid.(%) :	75
Pres(mmHg):	760	Smk.I.:	20
References :	SEPAR	Ethnic F(%):	100
Motive:			
Procedence:			
Techn. :			
Transducer:	Fleisch		

VC REPORT MANOEUVRE N: 1/1

PARAMETER		OBS	REF	(%)
VC	(l)	3.36		
VT	(l)	1.11		
ERV	(l)	0.72		

Comments : .....

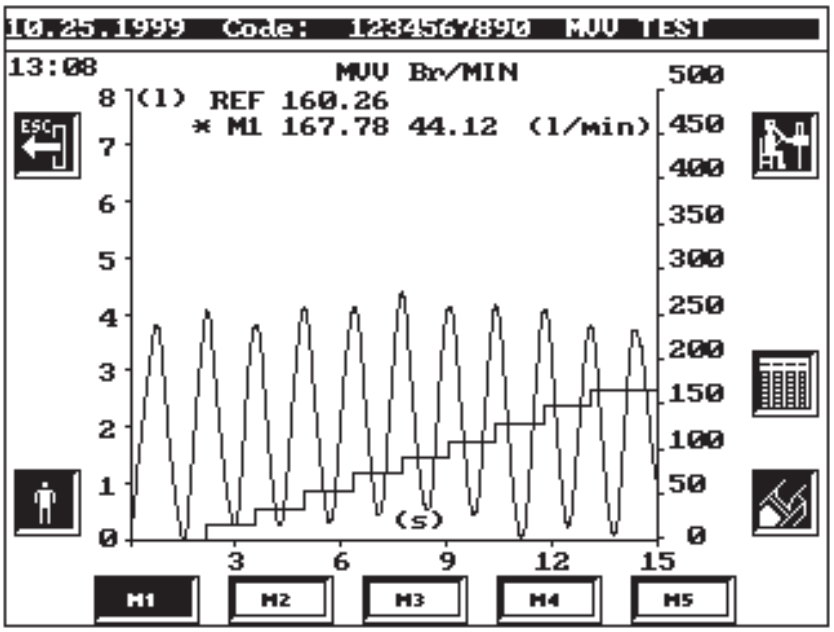
.....



1.10. PROCEDURE FOR THE MAXIMAL VOLUNTARY VENTILATION TEST "MVV"

The procedure to perform the **Maximal Voluntary Ventilation test "MVV"** is similar to the described in point **1.8. PROCEDURE FOR THE FORCED VITAL CAPACITY TEST "FVC"** with the following variations.

1st Enter the "MVV" test and perform a manoeuvre



2nd The presentation of the axis is made in VOLUME/TIME mode and incentive is not available.

3rd The maximum time for performing the manoeuvre is 15 seconds. They are put in order by the highest MVV.

4th The record of parameters and graphics is the displayed next, according to configuration. It is not allowed to superpose the manoeuvres in mode VC, as they will not give any complementary information.

DR. JOHN SMITH
SAINT PETER HOSPITAL. PNEUMOLOGY

DATOSPIR 120 - SIBELMED

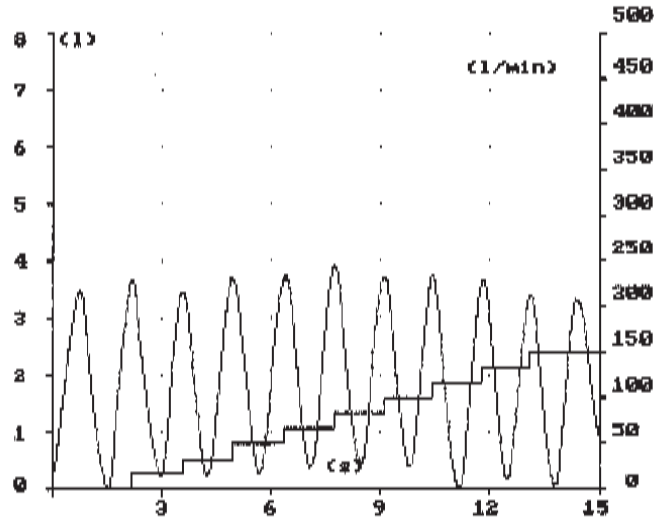
Code:	1234567890	Date: 30.10.1999	
Name:	CHARLES FORESTER		
Sex:	Male	Age(y):	43
Hght.(cm):	176	Wght(Kg):	92
Temp(ºC):	25	Humid.(%) :	75
Pres(mmHg):	760	Smk.I.:	20
References :	SEPAR	Ethnic F(%):	100
Motive:			
Procedence:			
Techn. :			
Transducer:	Fleisch		

MVV REPORT MANOEUVRE N: 1/1

PARAMETER		OBS	REF	(%)
MVV	(l/min)	150.82	160.26	94
Br/min		44.12		

Comments : .....

.....



1.11. PROCEDURE FOR THE POSTBRONCHODILATION TEST

The aim of this functioning mode is to have the spirometric results before (PRE)and after (POST) the application of a bronchodilator drug in the same report.

This test can be performed in modes FVC, VC and MVV, provided that a test in PREbronchodilation or basal mode has been performed and stored previously. See point **1.8.5. PRINTING AND/OR MEMORISATION OF FVC TESTS**.

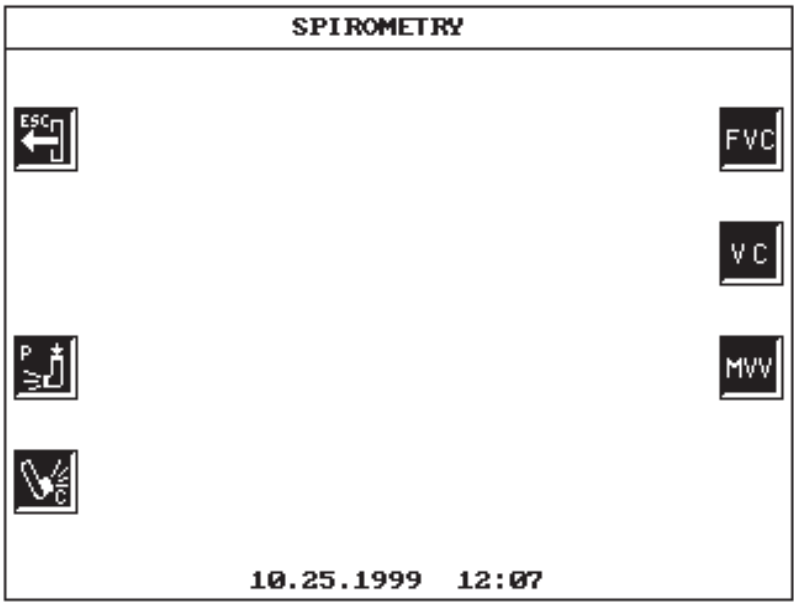
The sequence to perform the test is the following:

1st Perform a test FVC, VC or MVV before applying the dilation drug as described in the previous chapters.

2nd Memorise the PRE test to compare it in POST mode.

3rd Apply the drug to the patient in the corresponding dose according to the specialist criteria. Wait for the normalised time

4th Enter the POSTBRONCHODILATION mode from the SPIROMETRY screen by pressing F3

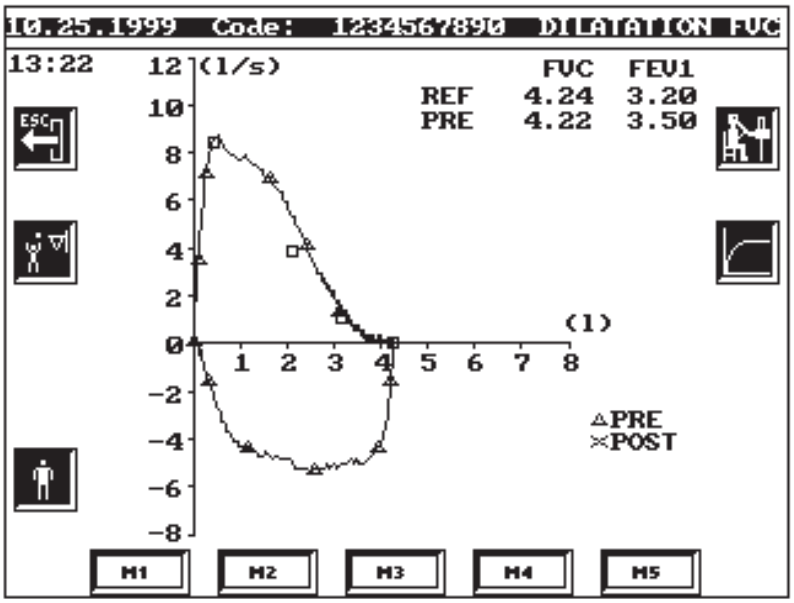


A similar display to this will appear,

This screen shows the memorised tests in PRE mode. The size of this memory is limited to:

6 manoeuvres FVC of 10 seconds each or
2 manoeuvres VC of 30 seconds each or
4 manoeuvres MVV of 15 seconds each or
a combination of these with a total time of 60 seconds.

5th Select a PREbroncho test to be compared, through keys F5 and F6 to place and F7 to validate. Next, the screen shows the graphic PRE with which the POST is being compared.



6th Then proceed according to the described in 1.8.2. and next points.

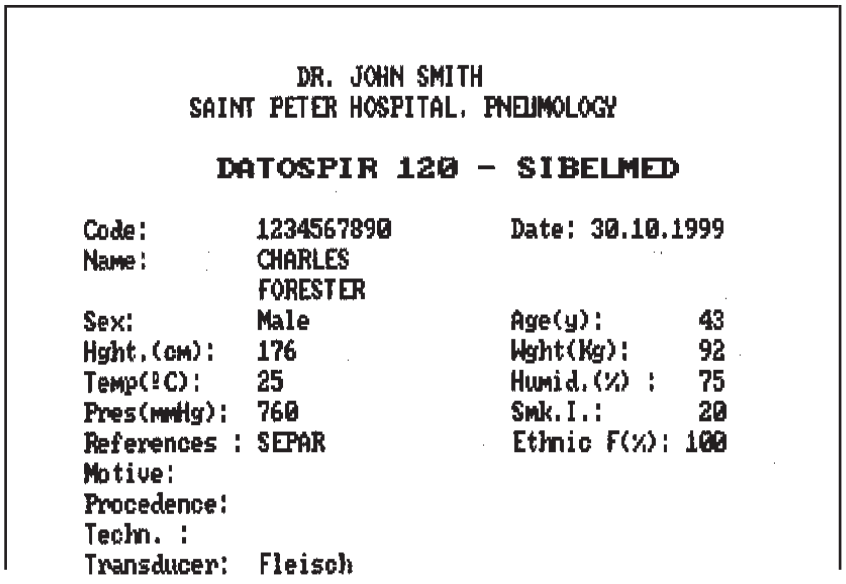
- In this case, the curve in POSTbroncho mode is compared to the stored curve in PREbroncho mode except in VC and MVV modes.
- The screen of data presents the observed values in PRE and POST

modes, as well as the method of comparison between both, according to the option selected in the configuration. See chapter 1.7.3. SPIROMETRY CONFIGURATION

% POND between PRE and POST
% Between REF and POST
% Between PRE and POST
Difference between PRE and POST

- The most used method of comparison is the % Weighted, which corresponds to **%POND = 100x2(POST-PRE)/(POST+PRE)**.
(See J.E. Cotes: Lung Function Assessment and Application in Medicine. Blackwell Sci. 4th Edition 1.979, p52-53).

The record of parameters and graphics is shown next


DR. JOHN SMITH
SAINT PETER HOSPITAL. PNEUMOLOGY

DATOSPIR 120 - SIBELMED

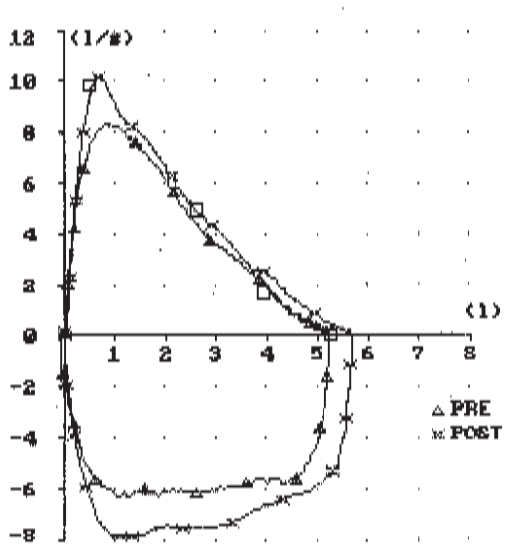
Code:	1234567890	Date: 30.10.1999	
Name:	CHARLES FORESTER		
Sex:	Male	Age(y):	43
Hght.(cm):	176	Wght(Kg):	92
Temp(ºC):	25	Humid.(%) :	75
Pres(mmHg):	760	Smk.I.:	20
References :	SEPAR	Ethnic F(%):	100
Motive:			
Procedence:			
Techn. :			
Transducer:	Fleisch		

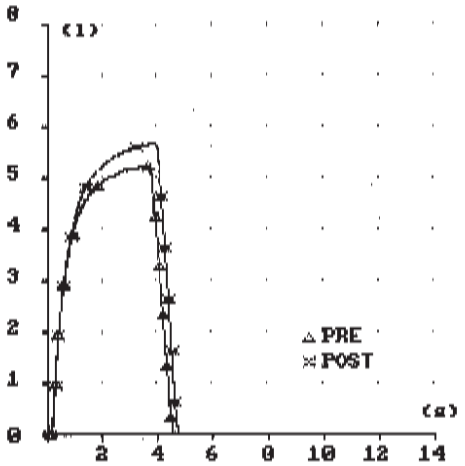
FVC REPORT MANOEUVRE N: 3/4

PARAMETER		PRE	REF	(%)	POST	%P
Best FVC	(l)	5.44	5.25	104	5.91	8
Best FEV1	(l)	4.44	4.04	110	4.64	4
FVC	(l)	5.24	5.25	100	5.69	8
FEV1	(l)	4.26	4.04	106	4.48	5
FEV1/FVC	(%)	81.20	77.40	105	78.83	-2
PEF	(l/s)	8.26	9.96	83	9.65	16
MEF50%	(l/s)	4.33	4.99	87	4.44	2
FEF25%-75%	(l/s)	4.04	3.89	104	3.96	-1
FET100%	(s)	3.89			4.13	6
MEF50% / MIF50%		0.69	0.66	105	0.58	-17
FEV1/PEF	(%)	8.58	6.64	129	7.74	-9
MIF50%	(l/s)	6.30			7.69	20
FIVC	(l)	5.34			5.67	6

Comments : .....

.....





1.12. PROCEDURE FOR THE BRONCHOCONSTRICTION OR BRONCHIAL PROVOCATION TEST

1.12.1. DESCRIPTION OF THE TEST

For the performance of the bronchoconstriction or bronchial provocation test is recommended, to those people who are not familiarised with this type of test, to check some bibliography about it. See The European Respiratory Journal (Volume 6, Supplement 16, March 1993) o “Normativa para los Tests de Provocación Bronquial Inespecífica” by the Sociedad Española de Neumología y Cirugía Torácica”, among others.

The bronchoconstriction tests consist of performing a forced spirometric test, after the application of different pharmacological stimulus to the patient, and then evaluate the changes produced in the spirometric parameters, specially the drop of FEV1. It must be taken into account that each test has several forced spirometric manoeuvres and it selects the best one to include in the summary report according to the criteria in the different standards.

Next, there is a short description of the different steps taking part in this type of test, from the point of view of the device use.

The steps described are not the only possible, although the most accepted ones. The spirometer **DATOSPIR-110/120** has the possibility to perform the test according to two different methods:

- Normal or continuous method
Consists of applying the patient a certain concentration for a specified time.

- Abbreviated method
Consists of applying the patient a certain number of inhalations of a certain concentration.

The procedure in both cases is the same. The variation lies in the way of applying the drug. In the first case the patient breaths the concentration for a while and in the second case we apply the inhalations to make it quicker.

The steps of the test are:

1st BASAL (BAS)
Perform a basal spirometry.

2nd DILUENT (DIS)
Apply a diluent with neutral PH to the patient, if convenient, and perform a

spirometry that compares to the basal.

3rd CONSTRIC. (BC1)
Apply the patient the first dose of bronchoconstrictor drug and after the stipulated time, perform the spirometry. It is compared to the DILUENT (DIS), or to the BASAL (BAS), if the diluent has not been made. Go to the next step to continue with the test.

4th CONSTRIC. (BC2)
The same as the last step, but with the second dose of drug.

5th CONSTRIC. (BC3)
The same as the previous step but with the third dose of drug.

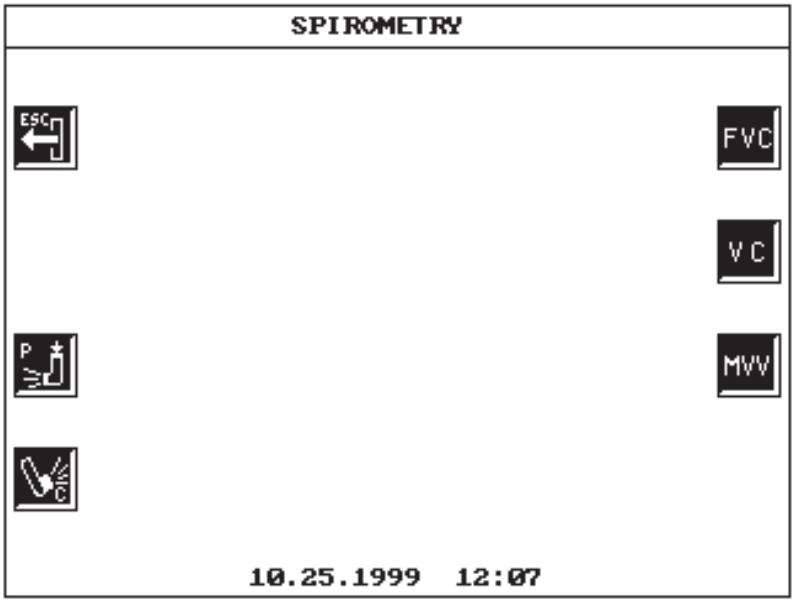
The process can be repeated until it is convenient. The system allows applying a maximum of 9 doses CONSTRIC. (BC9).

6th When the lung function parameters show a significant response, after a new confirmation, or according to the criteria of the operator who makes the test, the bronchial provocation test can be finished. The system analyses and shows the value of PD20 graphical and numerically.

7th CONST + DILAT
Finally, once the test is finished, the bronchodilator drug has to be applied to revert the resultant bronchoconstriction. Up two steps can be made in this modality.

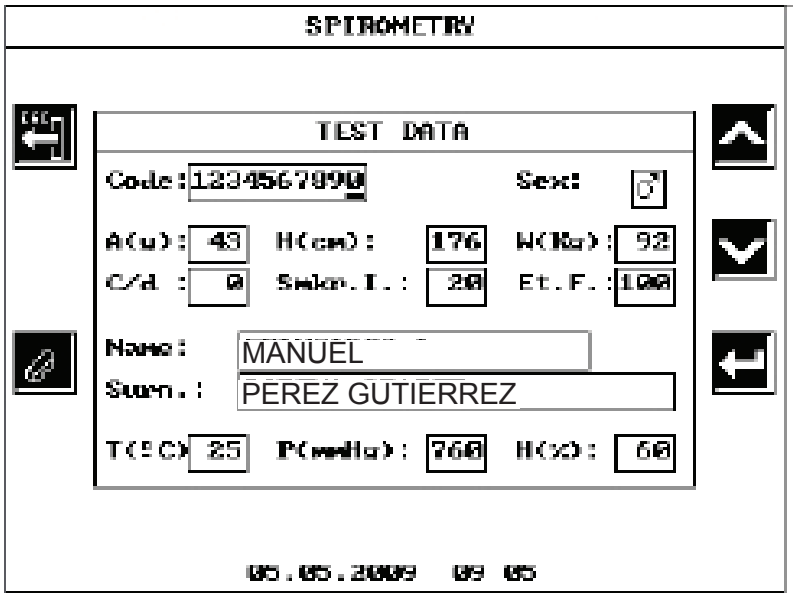
1.12.2. INPUT OF TEST DATA

Press key F4 in the next screen



There will appear

The procedure to follow for the input of the patient and environmental parameters is the same as the one described in point 1.8.1. INPUT OF PATIENT AND ENVIRONMENTAL PARAMETERS

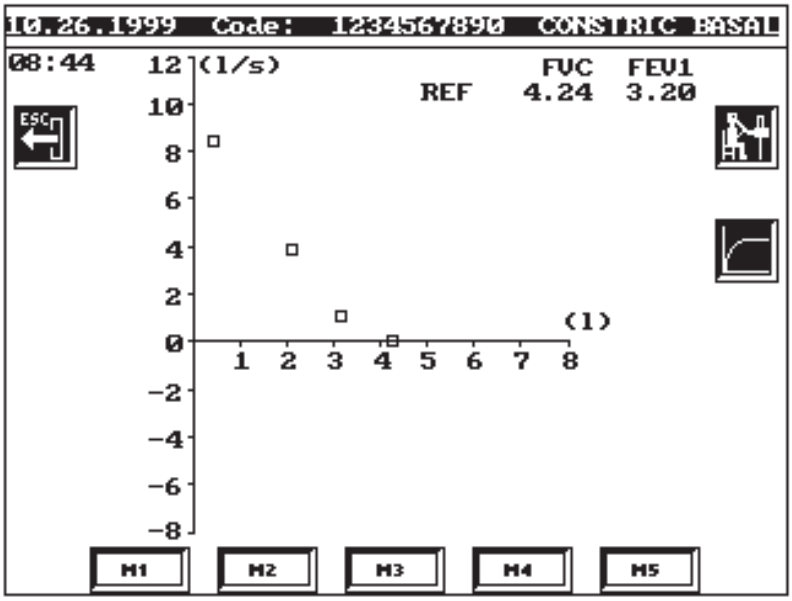


Once the previous data are filled in, press F7

- These data can be set up in the Configuration Program
Select the method or functioning mode
  Normal mode
  Short mode
- Select if diluent is going to be used
- Define the time between the application of the bronchoconstrictor drug and the start of the manoeuvres.

- Define the time between the application of bronchodilator drug and the start of the manoeuvres. Enter the initial dose of the bronchoconstrictor drug in mg/ml
- Register the bronchoconstrictor drug
- Register the bronchodilator drug

Once the previous data are filled in, press F7 key.



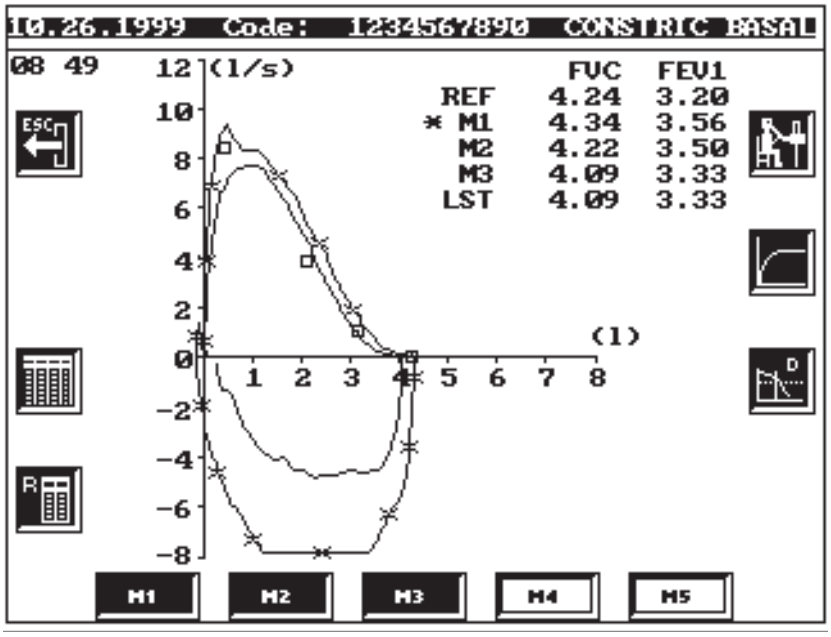
1.12.3. PROCESS OF THE TEST

As commented above, the Brochoconstriction test is based on performing forced spirometries after the application of different doses of drugs and controlling the drop of FEV1.

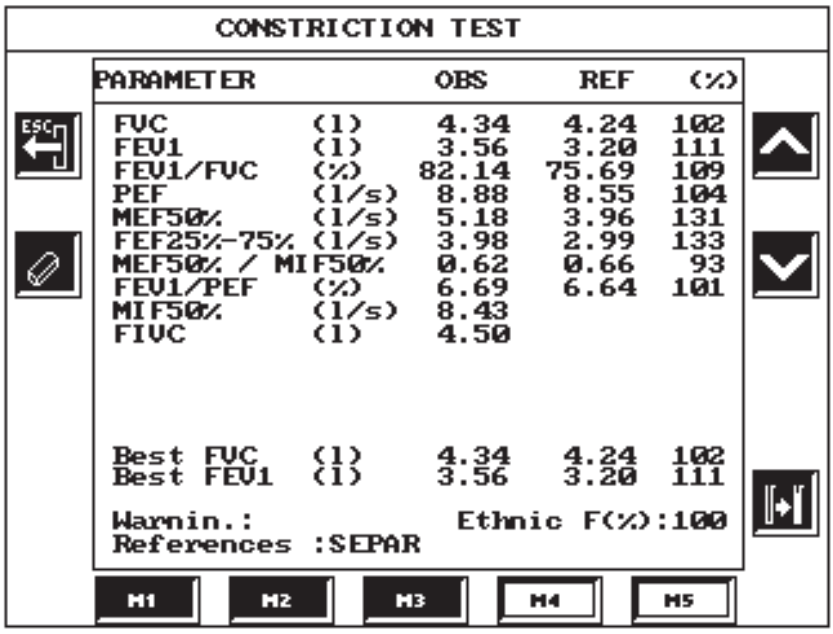
The steps for the test are the following:

1st Step: BASAL (BAS)

Start the process of forced manoeuvres as described in point **1.8.2. INPUT OF FORCED VITAL CAPACITY TESTS "FVC"**



Once the adequate manoeuvres are performed, press F3

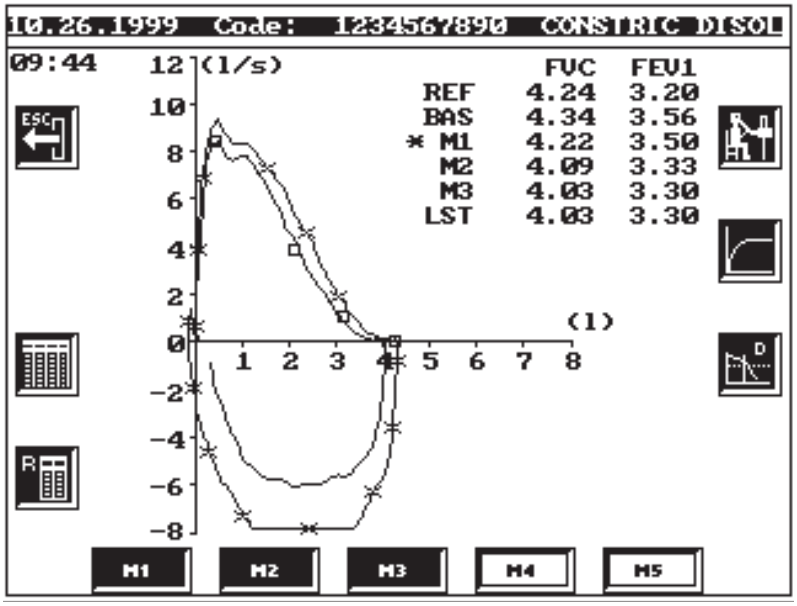


- The manoeuvres are compared to the values of the patient Reference
- F2 Deletes the selected manoeuvre
- F8 Stores the best manoeuvre and goes to the next step

Press F8 to store the manoeuvre and go to the next one

2nd Step: DILUENT (DIS)

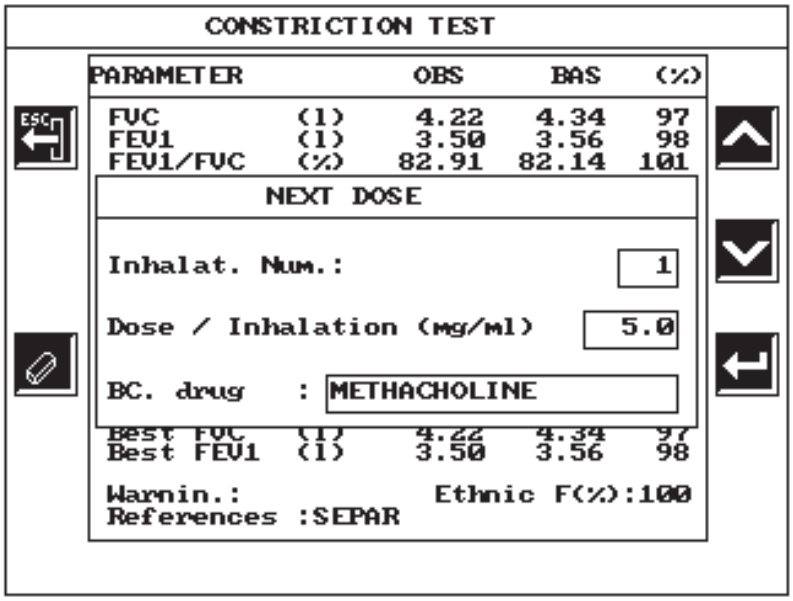
Apply the diluent with neutral PH to the patient, if you have selected this option. Start a new selection of forced manoeuvres, once the normalised time has passed.



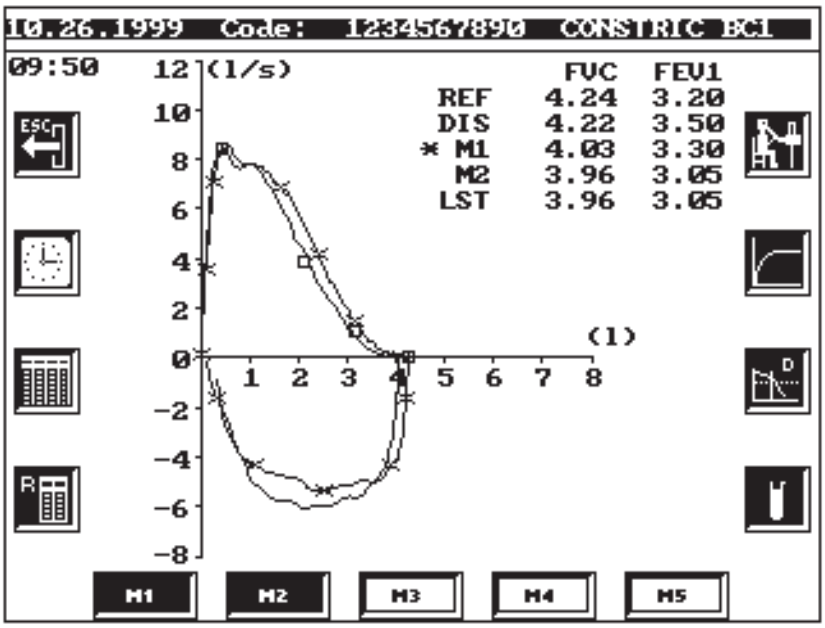
- The manoeuvres are compared to the stored basal
- F3 Gives access to the display of the data
- F4 Presents a summary with the data of the performed steps

After the adequate manoeuvres are performed, press F3 to display the data and again F8 to store the best manoeuvre and go to the next step.

3rd Step: CONSTRIC. (BC1)



Modify the data if necessary. Apply the first dose of bronchoconstrictor drug and press F7. Start another series of manoeuvres again.



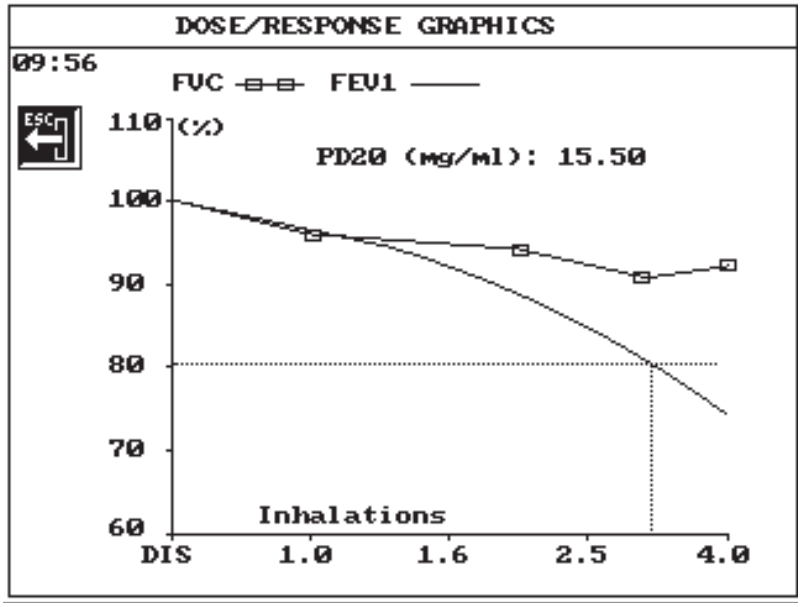
- F2 Initialises the chronometer to control the start of the manoeuvre after the application of the drug. It also blocks the acoustic alarm of the chronometer.
- F7 Presents the graphic dose/response of the performed steps
- F8 Enables to display or modify the medicine dose

Store the best manoeuvre in a similar way to the previous steps.

4th Step: CONSTRIC. (BC2, BC3, ... BC9)

The same procedure as in the previous step but for the second, third...tenth dose, as they are necessary.

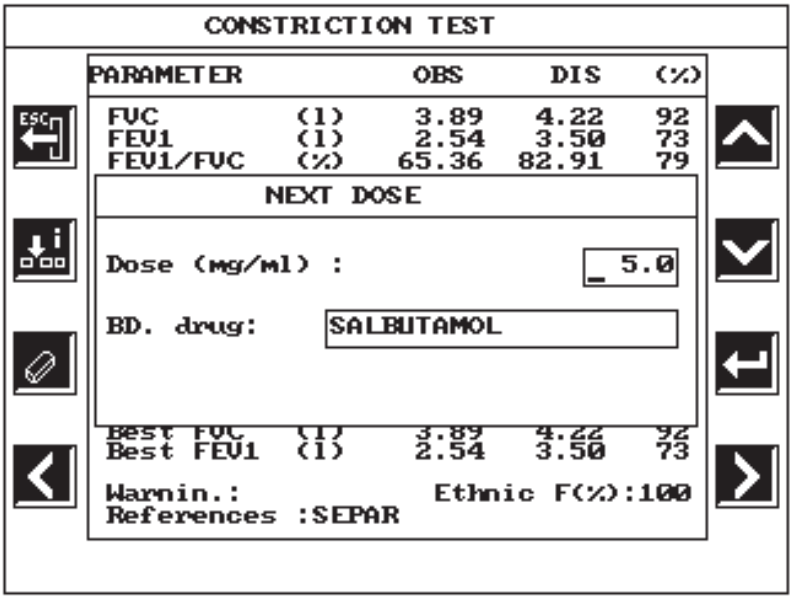
When the FEV1 value drops under 20%, regarding the diluent or the basal, if the diluent has not been made, the system warns about it and the graphic dose/ response shows the value for PD20



The graphic dose /response is shown mathematically adjusted through a process of logarithmic adjustment (y = C1 + C2 log (x)) if the coefficient of determination is better of 80%. In this case, the calculation of PD20 is made solving it in the adjustment equation. If the coefficient of determination is lower than 80%, the graphic is presented linearly and the calculation of PD20 is made by linear interpolation.

5th Step: CONSTRICTION + DILATATION (DIL)

When finishing this test, if you need to give the patient a bronchodilator drug to revert the resultant bronchoconstriction, press key F4 in the data screen of the previous display.

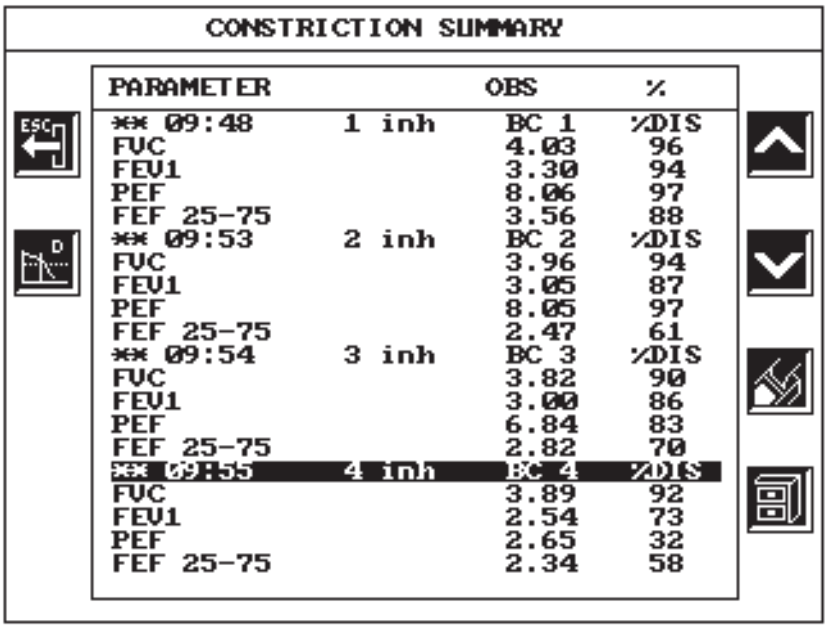


- Enter the data for the bronchodilator drug and press F7
- Apply the bronchodilator to the patient
- After the normalised time, perform a series of manoeuvres.
- Store the best manoeuvre, and repeat the previous process if necessary.

1.12.4. TEST SUMMARY

The summary of the bronchoconstriction test is presented in a graphic way (graphic dose/response shown before) or numerically (summary of the data shown next).

Go to the summary pressing key F4 on the screen of graphics.



F2	Presents the graphic dose/response
F5 y F6	Show the following values
F7	Prints the summary of the test
F8	Stores the test summary in the internal database

Take into account that the observed values are compared according to:

Basal with the selected Reference of the patient
Diluent, if made, with the Basal
Constriction with the Diluent, if made. Otherwise, with the Basal
Dilatation with the Basal.

1.13. PROCEDURE TO PERFORM THE CALIBRATION “CAL”

1.13.1. GENERAL OBSERVATIONS

As indicated above, the existent standards for spirometry recommend that all the spirometers have to be calibrated periodically. This is due to the alterations that can modify the characteristics of the electronic circuits and mechanical elements, causing a change in the calibration factors of spirometers. For this reason, we have included a calibration system from a signal of reference volume (for example, a syringe)

This calibration factor must take into consideration the changes in volume associated to the environmental conditions (temperature, relative humidity and barometric pressure). The most influent factor is the temperature and the humidity degree.

The **DATOSPIR-110/120** has incorporated a Calibration Program which enables easy and quickly (less than two minutes) to verify and self correct the measurements deviations. This is made from the pattern volume or reference, for the quality control of the different spirometric tests.

The periodicity of the calibration is left to the user criteria. SIBEL S.A., as manufacturer, according to the different standards, recommends performing the calibration daily or weekly.

1.13.2 TYPES OF TRANSDUCERS

The **DATOSPIR 120** can work with three different types of transducers:

Neumotachometer type Fleisch
Transducer type turbine
Transducer type disposable of mesh

The neumotachometer type Fleisch is the system of flow measurement of the greatest acknowledgement in the pneumology field, for its great reliability, reproducibility and duration.

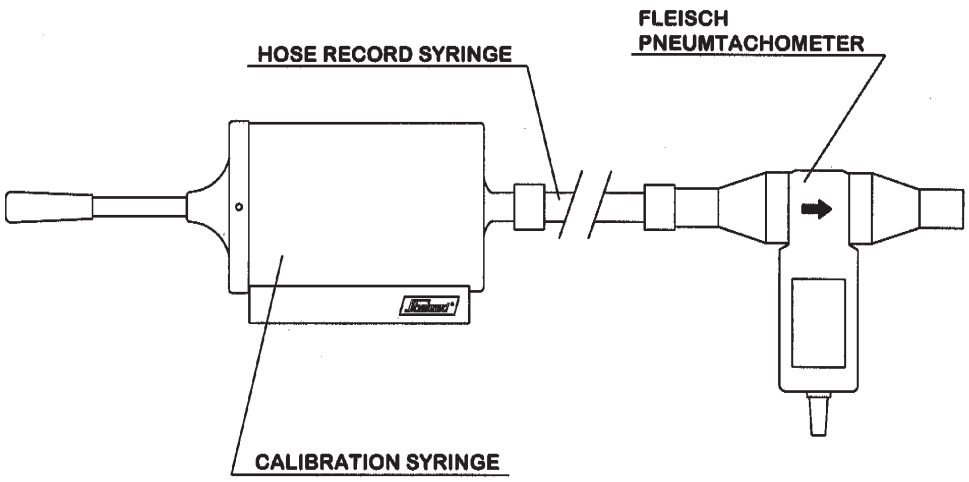
The transducer of turbine is a system with a good reliability, being its duration limited to the use and care.

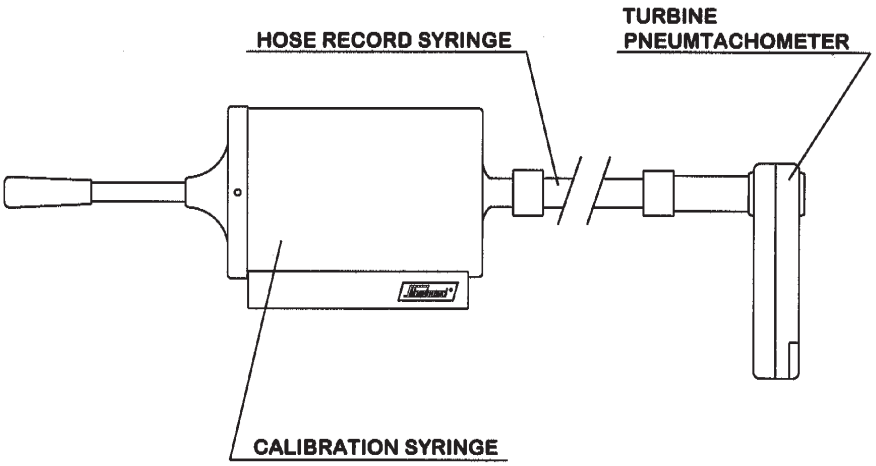
The transducer type disposable is an element with great reliability and reproducibility, adequate for its use in those cases where it is necessary to avoid possible infections among patients due to undetected or non eradicated infections because of lack of cleanness in the neumotachometer or transducer used.

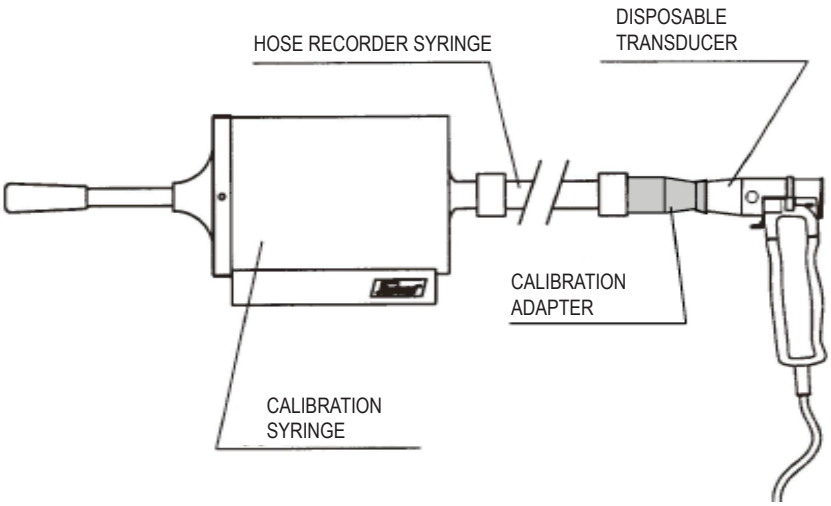
1.13.3. PROCESS FOR CALIBRATION

The steps to follow for the calibration are the following:

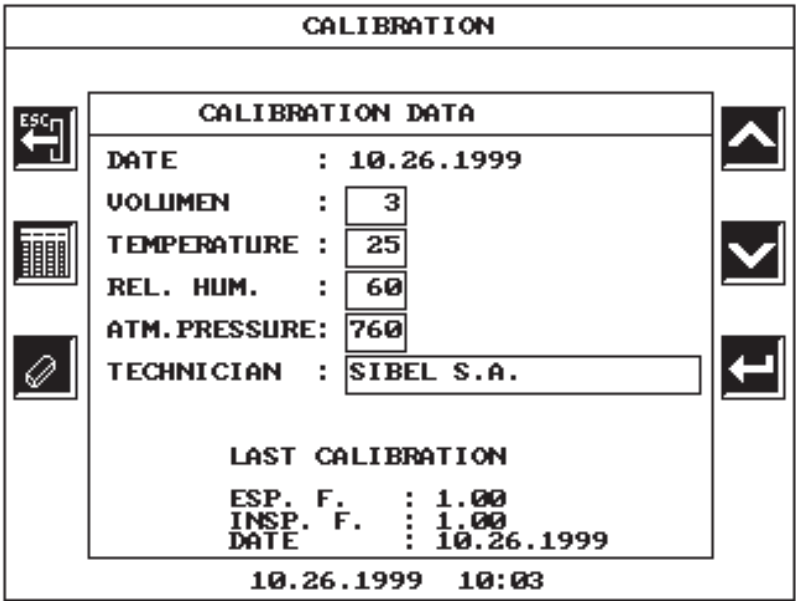
1- Connect the neumotachometer or transducer to the syringe inserting a tube of 1 metre long to avoid the influence of the turbulence caused by the sudden output of air, according to picture.







2- From the Main Menu screen, press F3 key.



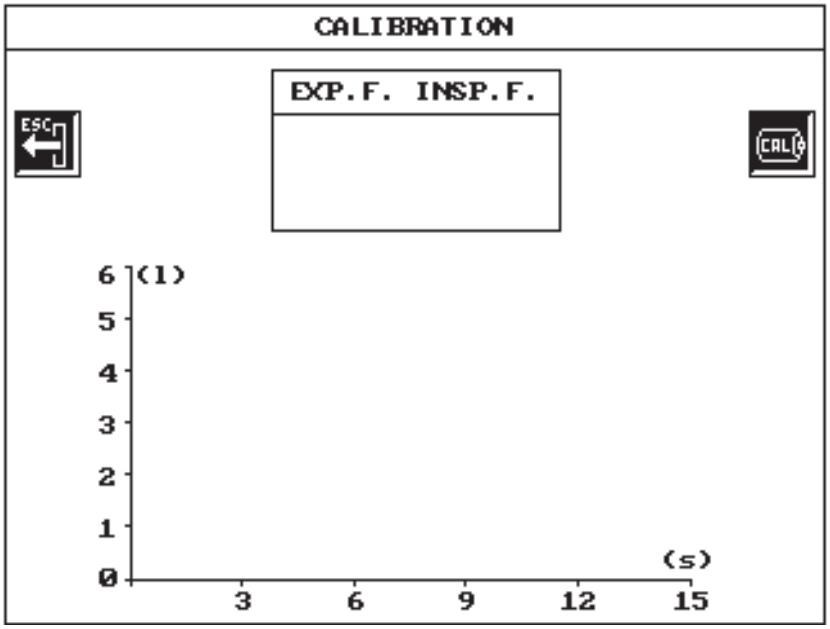
F2 Record of last calibrations
F3 Deletes a field or character according to situation.
F5 y F6 Takes back the cursor to the previous field or takes it forward to the following field
F7 Validates the entered data and goes to next screen

3- Fill in the data of the screen according to:

- Date: automatically taken
- Calibration volume (l): Volume in litres of the syringe to be used, between 1 and 6 litres.
- No. of pulses: (Only in the case of turbine) Number printed in the turbine corresponding to the number of pulses/turn.
- Temperature (°C): Value of the room temperature in °C.
- Humidity (%): Idem of the relative humidity in %
- Pressure (mmHg): Idem of the environmental pressure in mmHg
- Operator: Name or code of the person performing the calibration, if wanted

The data of the last calibration (expiratory and inspiratory factor and date) are not modifiable. It presents the data available in the device.

Press key F7



4- Make sure that the neumotachometer is at room temperature. If not, wait for some minutes or cool it up with air.

5- Press key F5 of the previous screen and start the process of calibration emptying out the syringe for **two or more consecutive** cycles (a cycle is the emptying plus the filling of the syringe). The piston of the syringe must move, in the emptying and in the filling, the total volume taken as a reference. If this is not made properly, the device will detect it as “incorrect manoeuvres”. Moreover, it is convenient to make this process regular and uniformly, without causing too high or low flows. The time of each cycle must not be less than three seconds or more than six.

6- The screen shows the expiratory and inspiratory factors taken by the device. If they are inside the l 2% , it will show that the system is calibrated. Otherwise, repeat point 5.

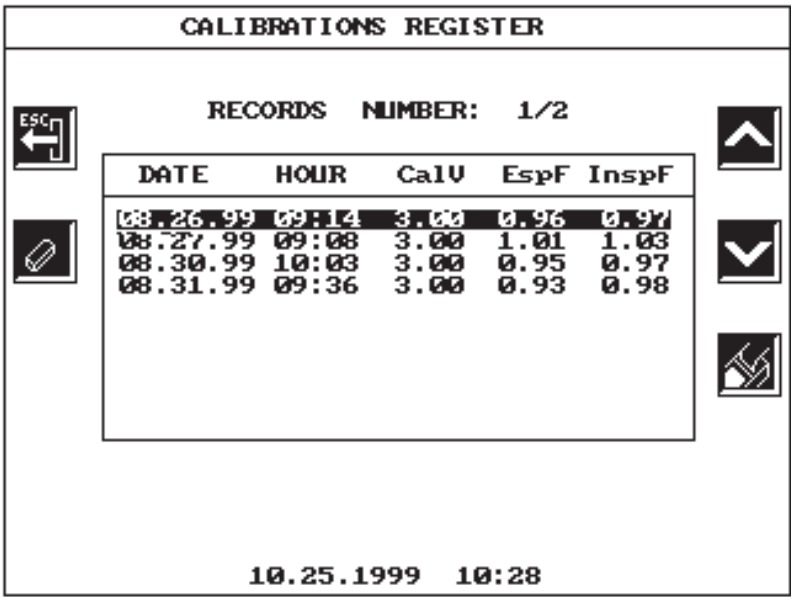
7- Once the calibration is finished, quit the Calibration Program and enter the Spirometry Program to start the tests.

Note:
If, when introducing the calibration parameters in point 3, the “Calibration volume (l):0” is assigned, the system takes the calibration factors “F. EXP and F.INS:1.00” corresponding to the original manufacturer calibration. It is convenient to use this calibration only as orientative, if a syringe is not available.

1.13.4. CALIBRATIONS RECORD

The spirometer has a record with the expiratory and inspiratory factors of the **last performed calibrations**. This is useful for those centres that require a quality control of the used processes.

For this purpose, press F2 on the first screen of the calibration process.



F2 Deletes a record
F7 Prints the existent records

The displayed information is:

Number of available records
Date of calibration
Time of calibration
Volume of calibration
Expiratory factor
Inspiratory factor

1.14. INTERNAL DATABASE

The **DATOSPIR-110/120** has an Internal DataBase, (standard or optional, depending on model), to store the different tests performed with the device. Then, it enables to display, print and / or transfer the tests to a PC or other computer systems for storage or management.

The information of the base is kept although the device is disconnected from the mains.

There are two databases with the same functions but different capacities:

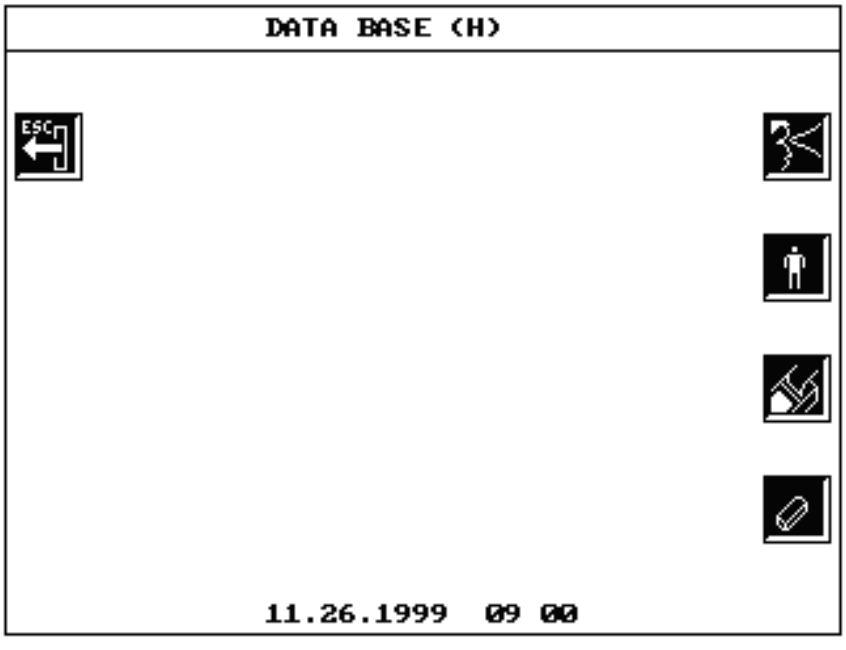
DataBase "L"
DataBase "H"

The tests to be stored, taking a six second FVC as reference, are:

	With graphics		**Without graphics**
	Fleisch/Disposable /turbine	Fleisch/Disposable	Turbine
DataBase "L"	150	150	150
DataBase "H"	400	900	1500

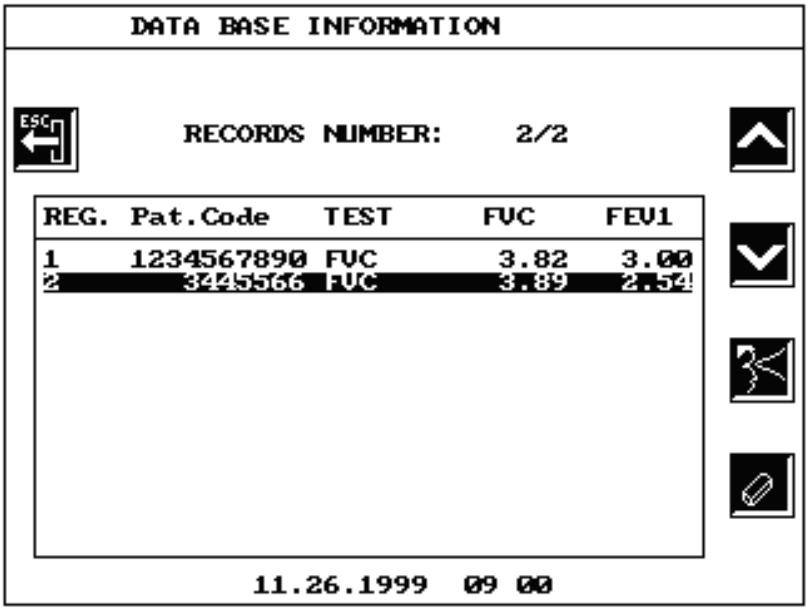
The test storage has been described in the corresponding points for each test.

From the Main Menu screen, press F1.



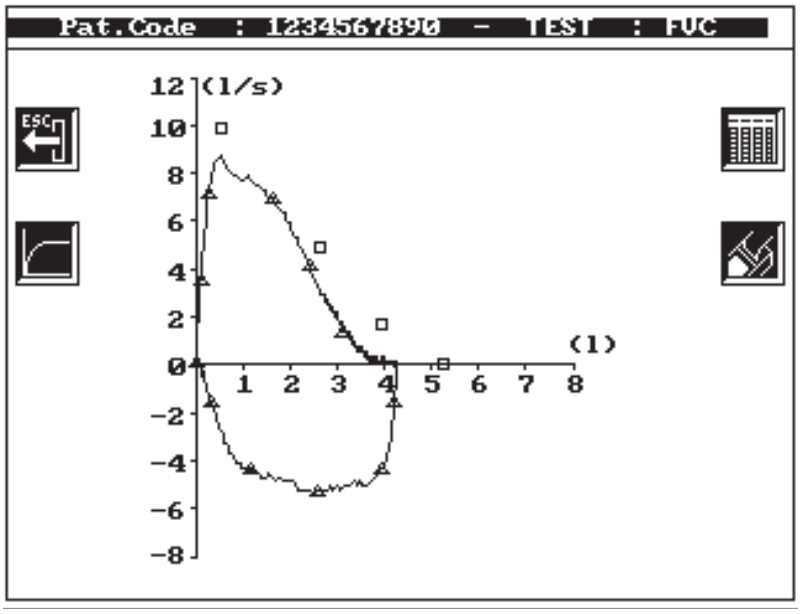
F5 Displays the stored tests
F6 Search for patient code
F7 Prints the stored tests
F8 Deletes all the stored tests

Press F5



F5 and F6 Select the test
F7 Displays the selected test
F8 Deletes the selected test

Use numeric keypad to select a record
Select a test and press F7

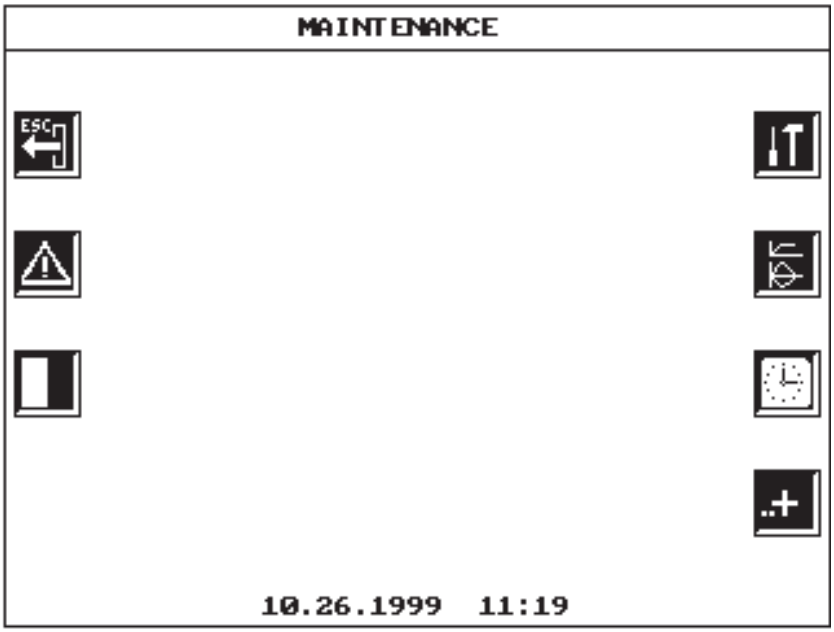


F2 Changes the type of graphic
F5 Presents the test data
F6 Prints the test

As commented above, the internal database information can be transferred to a PC or to other computer systems, in order to store or manage it. Its description is made in point 1.16. COMMUNICATIONS SYSTEM

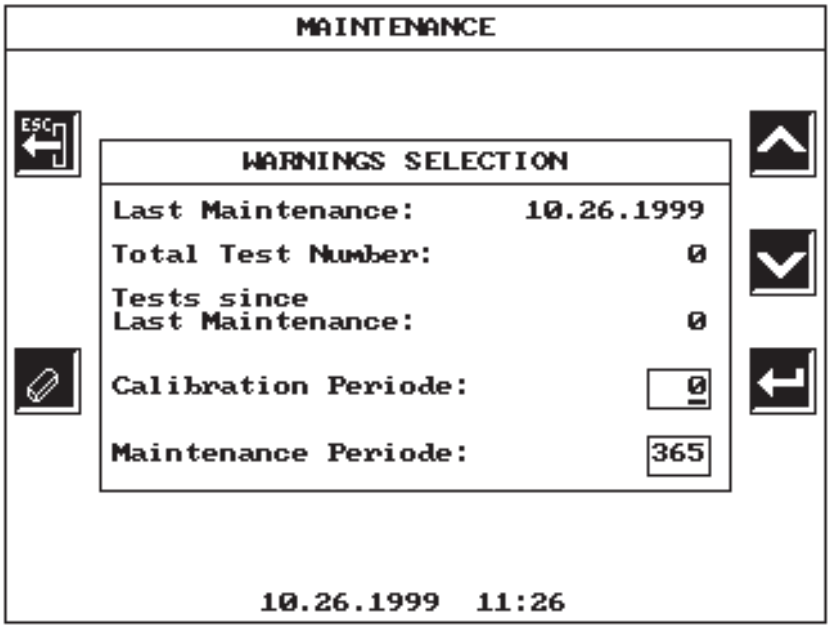
1.15. MAINTENANCE PROGRAM

The device has a maintenance program that enables to adjust and / or verify the functioning of certain options.
From the **Main Menu** screen, press F4



F2 Activates the warnings of calibration and /or maintenance
F3 Adjusts the screen and printer contrast
F5 Device's auto-check
F6 Check with pre-recorded pattern curves
F7 Updating of Time and Date in the calendar clock
F8 Several options

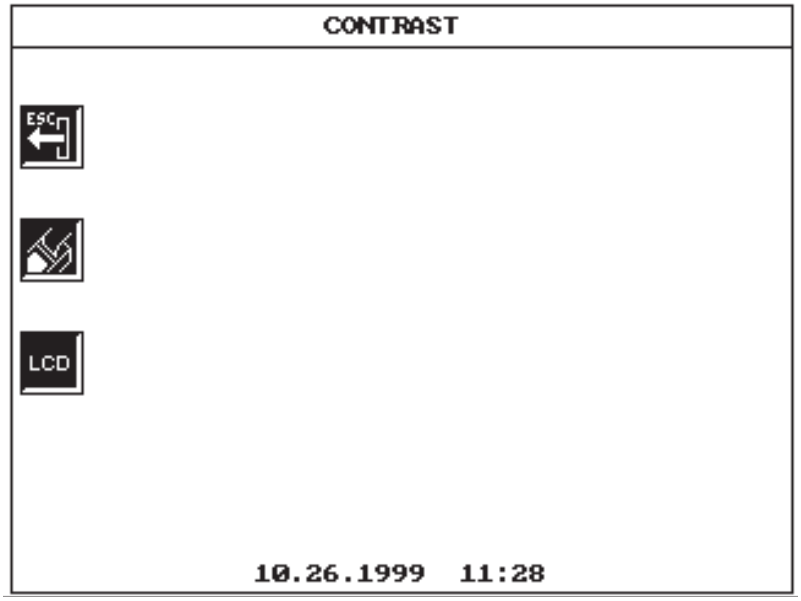
Press F2,



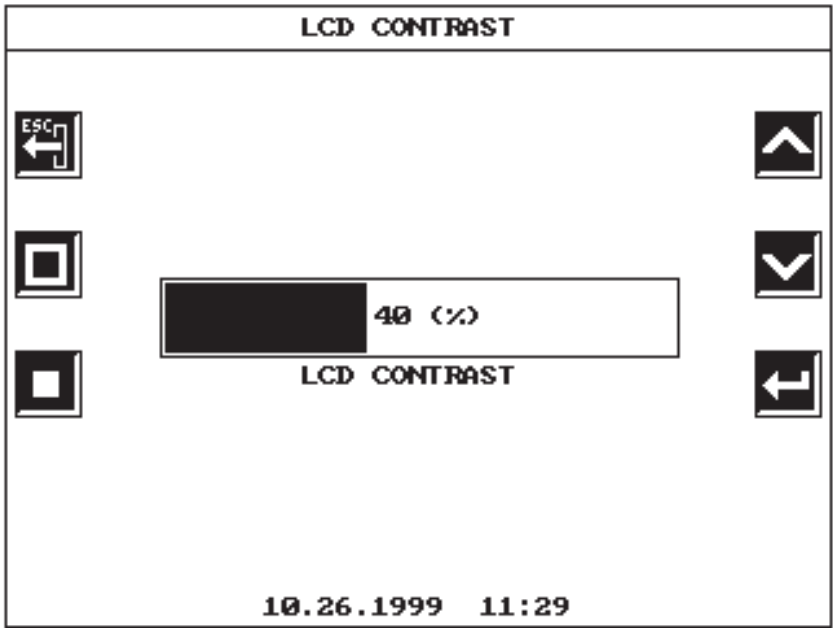
This option informs about the performed tests and enables to define the periods in days between calibrations or between preventive maintenance of the device The key F3 deletes and F7 confirms the data.
If the maintenance or calibration are not carried out within the specified days, the device warns by displaying a label in every start.

If 0 days are introduced, it will not warn in any case.

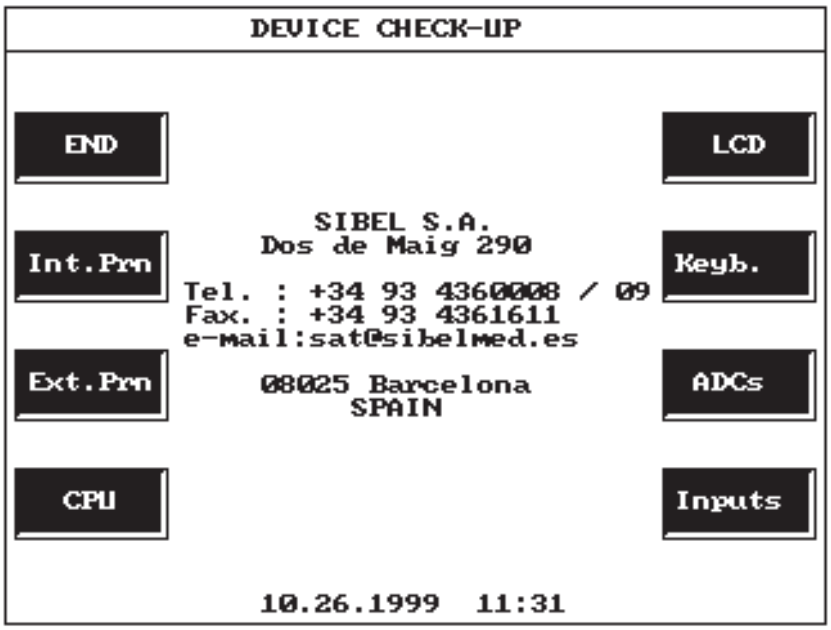
Press F3 on the maintenance screen



F2 Modifies the contrast of the internal printer
F3 Modifies the contrast of the LCD screen



Press key F5 on the maintenance screen



This option enables to check up different parts of the device.

Internal printer

10 lines of characters in alphabetic order will be printed.

External printer

The user should connect an external printer and select between HP PCL or IBM Graphics. The SIBELMED logo, the header lines and 10 character lines will be printed.

CPU

It calculates the Flash program Checksum and the bios program checksum. (For more information consult with the After-Sales Service. It will display a warning if there are errors in external or internal RAM.

LCD

It performs a test for the LCD, the beeper and the keyboard LED, following 5 steps.

- 1st displays a BAR graphics.
- 2nd shutdowns the LCD backlight during 2 seconds.
- 3rd inverts the displaying mode in the LCD during 2 seconds.
- 4th performs a LCD contrast sweeping.
- 5th performs 7 beeps from lower to higher frequency with a LED blinking.

Keyboard

The test finishes showing the message “Correct Test”, when all the keys (except ON/OFF) are pressed. The test can be aborted by pressing F1 twice.

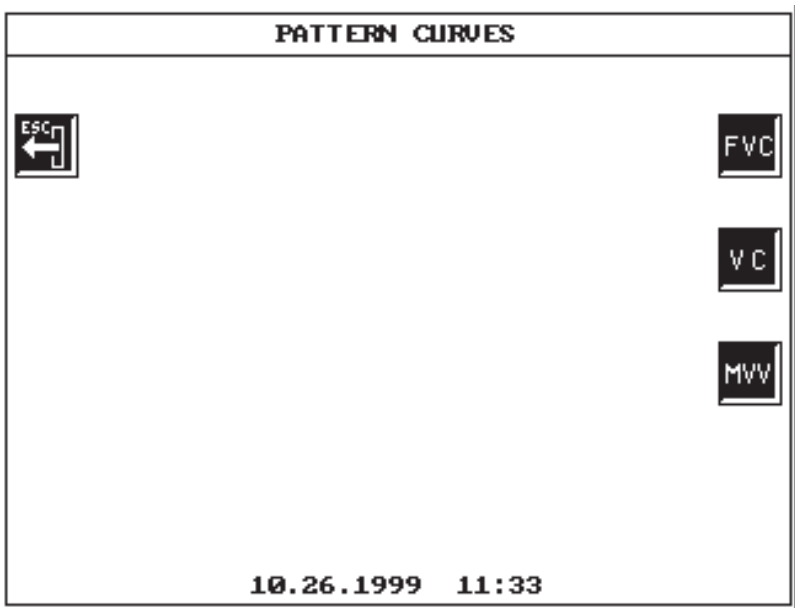
ADC’S

It shows which transducer is connected to the device, and the input voltage of this channel. In a second part, it displays the values of different parameters, and shows if the read values are or not correct.

Inputs

It shows if it is connected or not the external power supply, the weather station, the MEP-MIP transducer and the external printer; and the internal printer header status and its paper status.

Select the option and follow the instructions of the screen.
Press key F6 on the maintenance screen.



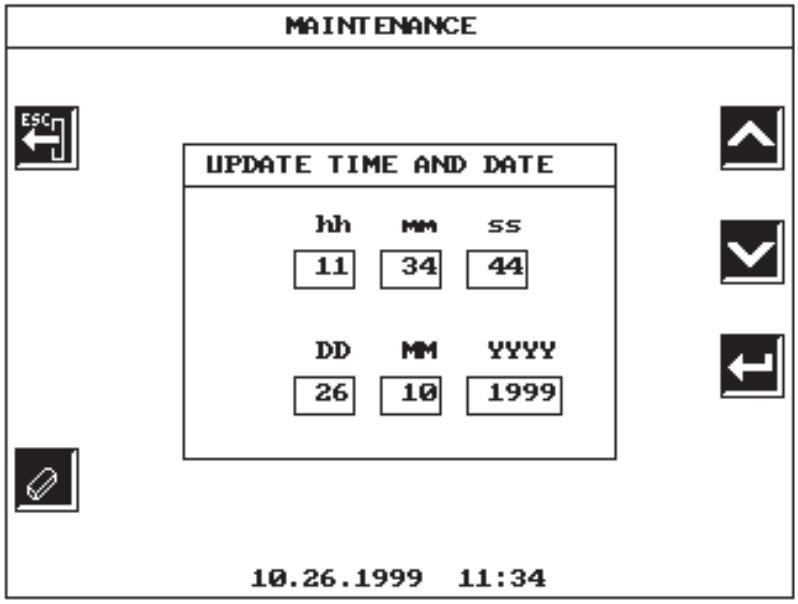
It has some pre-recorded curves to verify the functioning of the device.

- FVC two curves (No.1 and 2)
- VC one curve (No. 1)
- MVV one curve (No. 1)

The transducer stage is not checked with these curves, as for this it is necessary to enter a curve of real flow.

Select the option and follow the instructions on the screen, similar to the procedures of FVC, VC and MVV. With these curves you will be able to handle the device as if they were real curves of patients.

Press F7 key on the maintenance screen, to update time and date.



1.16. COMMUNICATIONS SYSTEM

One of the great qualities of **DATOSPIR-110/120** is its Communications System. It enables to transfer data to other systems:

Transfer Data of the Device Check up
Update the Software from a PC
Transfer the Tests of patients to a PC
Export Tests of patients to other Management Systems

All the communications system is performed through the RS232C serial channel in the device and through the corresponding software, standard or optional.

1.16.1. TRANSFER OF DEVICE CHECK DATA AND OF THE DATABASE

The **DATOSPIR-110/120** has a program that auto-checks the functioning of certain parts of the device, displaying the information on screen and storing it in an internal file.

The available information is:

Hardware Check
Software Check up
Device configuration
Record of Calibrations
Test of FVC with pattern curve

If some problem is detected and the user cannot solve it, the first alternative is to send the auto-check information to the After-Sales Service of **SIBEL S.A.** or your distributor, who will analyse and evaluate the cause of the problem, or will propose the adequate solution.
Spirometry Software Sibelmed W20 (in demo mode or enabled) **is required to transfer this information**. The program in demo mode is included as standard with the equipment.

The process to follow is this:

1. Start the **DATOSPIR-110/120**. From the Main Menu screen, press **F4 key MAINTENANACE** and enter the option F5 Auto-check.

Execute all the sub-options available, following the indications of the screen.

2. Interconnect the device with the **«PC CONNECTION LINK»** and the PC through the serial port.

3. Run the previously installed **W-20 Spirometry Software**, making sure that the DATOSPIR 110/120 is selected in Configuration - Links and access the Configuration - Utilities - Download Data option.
The transferred information is saved in the DATA directory of the application, in the files:

4. If you want to view the information of any of the files, load them using MICROSOFT EXCEL.

5. Load the files to your normal e-mail programme and send to the **SIBEL S.A. AFTER-SALES SERVICE or your Distributor**, who will analyse them and contact you to solve the problem presented.

If you do not have e-mail, you can print the data and send it by FAX.
If you do not have e-mail, you can print the data and transfer them through the FAX.

1.16.2. SOFTWARE UPDATING

Flash can be updated for a new version of the programme (in which improvements have been included) or to add another option to the equipment.
In the case of the latter, SIBEL, S.A. will provide a new update key.

In case of the former, consult the key in the equipment before starting the update process.

1. With the **DATOSPIR-110/120** working, from the main menu, press F4-Maintenance, and then press F8-Other Options. Register the updating password required in the PC.

2. Stop the DATOSPIR-110/120 and start it while pressing key F5.

3. Enter the password **120**.

4. Copy the new file provided by SIBEL containing the update (D12***.tsk) to the **\FIRMWARE** directory of the application (W20).

5. Run the **W-20 Spirometry Software**, access the Configuration - Links option and check that **Datospir 110/120** is selected.

6. Access the Configuration - Utilities - Update Flash option (the **W-20 Spirometry Software** in «demo» mode provided on purchasing the equipment is enough).
A dialogue box will open where the **update key** (that previously consulted if this is a version update or that provided by SIBEL if it is an option update) must be entered.

7. The new programme will be transmitted. The process may take around **10 minutes**, depending on the PC.

8. Switch off the **DATOSPIR 110/120**.

1.16.3. PATIENT TESTS MANAGEMENT IN THE PC

If you want to display, print, manage and /or store the tests in the PC, it is necessary to have the **SPIROMETRY SOFTWARE W-20**.

The process to follow is:

1 Store the tests in the internal database of the device.

2 Set up the **SPIROMETRY SOFTWARE W-20**, as detailed in the **Software W-20 Use Manual**.

3 Load the Database data from the PC using the W-20 Software **BATCH** option.

4 The screen shows a list of the tests transferred and you can select those to be imported to the **PC Database** selected in the W-20 Software Configuration option.

5 The screen displays a list with the tests transferred. The ones to be imported to the **PC DataBase** are selected in the option Software Set-up W-20.

6 From that moment, you can select, display or print any imported or transferred tests to the PC.

1.16.4. EXPORT OF TESTS TO OTHER SYSTEMS

The spirometer DATOSPIR-110/120 has the possibility to export previously stored tests in the **Internal DataBase** to other management systems of each particular hospitalary centre.

The device presents the information in **mode delimited by inverted comas**, which makes it compatible with multiple systems.

This export of tests is carried out in a similar way to the described in point 1.16.1.

The information is available in the following files:

PRUEBAS.TXT contains the database tests
GRAFICAS.TXT contains the graphics in mode Flow/Time

The graphic file, as indicated, contains graphics for each test in mode **Flow / Time**. If you want to display the graphics in the new management system in mode **Volume/Time** or **Flow / Volume**, the following aspects have to be take into account:

- With the turbine transducer, the Flow signal is sampled at 25Hz and with the Fleisch or disposable transducers at 100Hz.

- In the Volume/Time graphic, the relation of the axis must be adjusted at 1 litre = 2 seconds.

- In the Flow/Volume graphic, the relation of the axis must be adjusted at 2 l/s = 1 l

If there is any doubt or consult, contact with the **Technical Service of SIBEL S.A.** or your distributor, who will explain the information you require.

1.17. SPIROMETRY SOFTWARE W-20 FOR PC

For the information related with the **Software W-20 (Optional), see the Software User´s Manual.**

2. 2. TECHNICAL SPECIFICATIONS

The specifications detailed below should apply according to the model that the user has. These models are detailed in the paragraph **1.3. MODELS OF SPIROMETER DATOSPIR-110/120.**

2.1. TYPES OF TESTS, FUNCTIONS AND SPIROMETRIC PARAMETERS

2.1.1. FVC FORCED VITAL CAPACITY

- Parameters:

* FVC	(l)	Forced Vital Capacity
* FEV.5	(l)	Forced Expiratory Volume in 0.5 seconds
* FEV1	(l)	Idem in 1 second
* FEV3	(l)	Idem in 3 seconds
* FEV.5/FVC	(%)	Relation
* FEV1/FVC	(%)	Relation
* FEV3/FVC	(%)	Relation
* FEV1/VC	(%)	Relation
* PEF	(l/s)	Peak Expiratory Flow
* MEF75%	(l/s)	Maximal Expiratory Flow when the 75% of FVC remains in the lung
* MEF50%	(l/s)	Idem, at 50% of FVC
* MEF25%	(l/s)	Idem, at 25% of FVC
* FEF25-75%	(l/s)	Forced mid-expiratory flow
* FEF75-85%	(l/s)	Forced mid-expiratory flow between 75-85% of FVC
* FET25-75	(s)	Forced expiratory time between 25-75% of FVC
* FET100	(s)	Forced Expiratory Time
* MEF50/MIF50	(-)	Relation
* FEV1/FEV.5	(-)	Relation
* FEV1/PEF	(-)	Relation
* MIF50%	(l/s)	Maximal inspiratory flow when the 50% of FVC has been inspired
* FIVC	(l)	Forced Inspiratory Vital Capacity
* FIV1	(l)	Forced Inspiratory Volume in 1 second
* FIV1/FIVC	(%)	Relation
* FEV1/FIV1	(%)	Relation
* PIF	(l/s)	Peak Inspiratory Flow
* MTT	(s)	Mid Transit Time
* PEF/PIF	(-)	Relation
* Vext	(l)	Extrapolated Volume with regard to the FVC
* MVVin	(l/min)	Maximum to indirect Voluntary Ventilation (30 x FEV1)
* FEV6	(l)	Forced Expirometry Volume in 6 seconds
* FEV1/FEV6	(%)	Ratio

- COPD (Chronic obstructive pulmonary disease) rate. Parameter that depends

on the number of cigarettes smoked a day, the age and FEV1. Indicates the risk of COPD.
- Age of the Lung Parameter that depends on the height and FEV1. Indicates the equivalent age of the lung.
- Diagnosis based on
- Miller´s Quadrant or Snider, Kory & Lyons
- Percentage of Deviation regarding reference values
- Reference values normalised to be selected between several standards
- Data of Patient Identification
- Environmental Data of temperature, pressure and relative humidity
- Graphics in FLOW/VOLUME and VOLUME/TIME mode
- Graphic incentive for children
- Warnings of manoeuvre acording to the ATS/ERS criteria
- 5 manoeuvres of the same test can be stored
- Acoustic and graphic indications for start and end of manoeuvres

2.1.2. SLOW VITAL CAPACITY

- Parameters

* VC		(l)	Slow Vital Capacity
* TV	(l)	Tidal Volume	
* ERV		(l)	Expiratory Reserve Volume
* IRV		(l)	Inspiratory Reserve Volume
* IC	(l)	Inspiratory Capacity	
* Ti		(s)	Inspiratory time
* Te	(s)	Expiratory time	
* Tt		(s)	Total time
* Ti/Tt		(-)	Relation

- Percentage of deviation regarding the reference values
- Normalised reference values to be selected between several standards
- Data for patient identification
- Environmental data of temperature, pressure and relative humidity
- Graphics in VOLUME/TIME
- 5 manoeuvres of the same test can be stored

2.1.3. MAXIMUM VOLUNTARY VENTILATION

- Parameters:

* MVV	(l/min)	Maximum Voluntary Ventilation
* Br./min	(Br/min)	MVV Breathing Rate

- Percentage of deviation regarding reference values
- Normalised reference values available between several standards

- Data of patient identification
- Environmental data of temperature, pressure and relative humidity
- Graphics in VOLUME/TIME mode
- 5 manoeuvres of the same test can be stored

2.1.4. BRONCHODILATATION TEST

- The same parameters as in the FVC
- Some comparison methods between PRE, POST and REF values
- Superposition of graphics PRE and POST

2.1.5. BRONCHOCONSTRICTION TEST

- Parameters

* FVC	(l)	Forced Vital Capacity
* FEV1	(l)	Idem in 1 second
* PEF	(l/s)	Peak Expiratory Flow
* FEF25-75%	(l/s)	forced mid-expiratory Flow

- Data of Patient identification
- Environmental data of temperature, pressure and relative humidity
- Continuous or shorter methods
- Deviation Percentage between Basal and dissolution
- Superposition of graphics in FLOW/VOLUME or VOLUME/TIME
- Stopwatch for controlling the steps
- Type of drug and accumulated dose
- Calculation of PD20 (FEV1) by mathematics adjustment or linear interpolation
- Numeric and graphic (dose/response) data summary on screen
- Link with bronchodilatation test

2.1.6. PULSE OXIMETRY SpO2

The technical specifications are detailed in Annex: PULSE OXIMETRY.

2.1.7. MAXIMAL RESPIRATORY PRESSURES

The technical specifications are detailed in Annex: MAXIMAL RESPIRATORY PRESSURES

2.1.8. CALIBRATION

- Calibration Program for dynamic tests with syringe of 1 to 6 litres of volume.
- Register of the last calibrations
- Indicación, if wanted, of calibration warnings

2.1.9. CONFIGURATION PROGRAM

- PATTERN configuration selectable by the user
- Language, printer, report header, etc. configurable by the user.

- Spirometry configuration
  - Reference parameters
  - Observed parameters
  - Graphic selection
  - Diagnosis Selection
  - Report configuration
  - Etc.
- Pulse oximetry configuration
- Maximal Respiratory Pressure

2.1.10. INTERNAL DATABASE

- Storage of spirometric test, pulse oximetry and maximal respiratory pressures.
- Two types of database according to their storage capacity

2.1.11. CLOCK-CALENDAR

- Hour, minute, second
- Day-Month-Year
- Stopwatch

2.2. MEASUREMENT SYSTEM

2.2.1. TRANSDUCER TYPES

Fleisch neumotachometer: linearized by software. It can be disassembled for cleaning and sterilisation. It includes a semiconductor differential manometer with internal temperature compensation. Fleisch lifetime of 1700 disinfections or 7 years.

Turbine transducer volumetric bi-directional axial turbine with optoelectronic turning sensor that can be disassemble for cleaning and sterilisation. The pivot turns over sapphire shaft to obtain high reproducibility and duration. Turbine lifetime of 600 disinfections or 3 years.

Disposable grid transducer (Lilly) linearized by software and calibrated for disposable use. It includes a semiconductor differential manometer with internal temperature compensation.

Mesh disposable transducers (Lilly) of SIBELMED, are the most reliable on the market, as they are individually pre-calibrated at the factory where a calibration factor is associated with them. This calibration factor must be introduced into the

spirometer. (Only one factor for pack of transducers).
If in the future you acquire a new pack of disposable transducers, remember to update the calibration factor in the spirometer

2.2.2. RANGES AND MEASURES

	Fleisch	Turbine	Disposable
- Measuring scale			
Flow (l/s)	0 to ±16	0 to ±16	0 to ± 16
Volume (l)	0 to 10	0 to 10	0 to 10
- Dynamic Resistance to flow			
kPa/l/s	< 0,03	< 0,06	< 0,06
- Accuracy			
Volume (whichever greater)	3% or 50 ml	3% or 50 ml	3% or 50 ml
Flow (whichever greater)	5% or 200 ml	5% or 200 ml	5% or 200 ml
Timer: best of	0,5%	0,5%	0,5%
- Volume Resolution (ml)	< 1	< 6	< 3
- Sampling frequency (Hz)	100	25	100

2.3. MICROCONTROLLER

- System microcontroller
  . Hitachi's H8532
- Volume accumulating time
  . Five FVC graphs of 25 seconds maximum each one
  . Five VC graphs of 45 seconds maximum each one
  . Five MVV graphs of 15 seconds maximum each one
- FVC expiration start
  . By retrograde extrapolation method
- FVC expiration end:
  . When the accumulated volume in the last second is less than 0.025 litres
- FVC manoeuvres selection
  . By the maximum of FVC+FEV1 criteria or as the operator wants
- Parameter selection
  . FVC and FEV1: the greater ones between the stored tests. Rest of parameters: of the selected manoeuvre, being recommended the manoeuvre of greater FVC+FEV1.
- Keyboard:
  . All the instruction, data, etc. that the operator transmits to the microprocessor are performed by pressing a membrane keyboard.
- Communication channel RS 232C

2.4. DATA DISPLAYING

- LCD (Liquid Crystal Display) with 320 x 240 pixels and viewing area of 120x90 mm
- By means of an internal thermal printer of 58 or 112 mm wide.
- By means of an external printer
- By means of a PC with the corresponding software

2.5. ELECTRONIC WEATHER STATION

- Temperature: 0 a 50 ºC ±1 ºC
- Pressure: 375 a 785 mmHg ± 5 mmHg
- Humidity: 0 a 100% ± 5%

2.6. GENERAL DATA

- Ambient Temperature:
Between 10 and 40 ºC.
(American Thoracic Society recommends 17 - 40 ºC)

- Relative humidity:
<= 85% (without condensation)

- Atmosferic pressure:
From 525 to 800 mmHg (from 3000 to - 400 meters aprox.)

-Storage Temperature:
-5 a 70ºC (Exception: storage temperature for termosensitive paper for internal printer: 5 a 40ºC

- Power supply:
220 V ±10% 50/60 Hz (others opctional)
Rechargeable battery: 1.5 Ah (Only for models without Fleisch)- Power : Below 25 VA

Size:
210 x 297 x 95 mm

- Weigth:
1.7 Kgr. aprox. Without accesories

- Life time:
7 years

2.7. APPLICABLE STANDARDS

1. Related to the product

MEDICAL DEVICE

93/42/CEE Directive (RD 1591:2009)

ELECTRICAL SAFETY

- EN 60601-1: 2006+AC:2010 Seg. medical equipment: Class I

EMC

- EN 60601-1-2:2007+AC:2010 EMC in medical equipment (Not vital support). See APPENDIX 1. ELECTROMAGNETIC COMPATIBILITY

SPIROMETRY

Standards:

- EN ISO 26782:2009/AC:2009 Equipment of Anaesthetic and respiratory resuscitation. Spirometers for measuring forced expiratory volume during a time interval in humans

- EN ISO 23747:2009 Spirometers for peak expiratory flow

Recommendations:

- SERIES ATS / ERS TASK FORCE:

No. 1. Miller MR, Crapo R, Hankinson J, et al. General considerations for lung function testing. Eur Respir J 2005, 26:153-161.
No. 2. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J 2005; 26: 319-338.
No. 3. V. Brusasco, R. Crapo and G. Viegi. Standardisation of the Measurement of lung volume Eur Respir J 2005;26:511-522

- Sanchis et al. Regulations for spirometry. No. SEPAR recommendations. 1. Arch Bronconeumol 1989, 25: 132-142)

USABILITY AND APTITUDE FOR USE

- EN 60601-1-6:2010 General requirements for safety. Part 1-6. Collateral standard: Usability

- EN 62366:2008 Application of engineering skills to use medical devices

VIBRATION AND TEMPERATURE

- Series EN 60721:1995 Classification of environmental conditions
- Series EN 60068:1999 Environmental testing

BIOCOMPATIBILITY

- EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices. Part 1.

SOFTWARE

- EN 62304:2006+AC:2008 Software for Medical Devices

DOCUMENTATION AND INFORMATION

- EN 1041:2008 Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2012 Symbols to be used with medical device labels, labelling andi nformation to be suplplied.

2. Related to the manufacturer

QUALITY

- EN ISO 13485:2012+AC:2012 Quality management systems. Requirements for regulatory purposes.
- EN ISO 9001:2008 quality management. Requirements
- EN ISO 14971:2012 Risk management in medical equipment

WASTE

- RD 208/2005 Electrical and electronic equipment and waste management. Transposition of WAEE 2002/96/CE Directive

3. To be satisfied by the user

DATA PROTECTION

- Compliance with LOPD and 95/46/CE Directive

WASTE

- RD 208/2005 Electrical and electronic equipment and waste management. Transposition of WAEE 2002/96/CE Directive

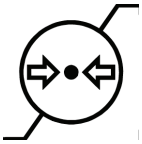
2.8. SIMBOLOGY

SERIAL NUMBER

MANUFACTURER
(The date of manufacture, name and address of manufacturer)

TEMPERATURE LIMITATION

HUMIDITY LIMITATION



PREASURE LIMITATION

DIRECTIONS FOR US

APPLICABLE PART B

LOT

EXPIRY DATE

CAUTION

LAND

STANDBY

DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC AGREEMENT TO THE WEE DIRECTIVE

DO NOT REUSE

3. FUNCTIONING PRINCIPLES

The **DATOSPIR-110/120** spirometer is an acquisition device for physical signals and a signal processor that gives information about the lung function. To perform the signal processing is necessary to change the physical magnitude to electrical. The units that perform this change are called transducers. The **DATOSPIR-110/120** has three different transducers: a) Turbine, b) Fleisch Neumotachometer and c) Disposable Lilly Neumotachometer.

The turbine transducer performs its function in two steps: The volume passes through the turbine and the rotor turns proportionally to the volume. The rotor turns are detected by the interruption of a infrared light beam which sensor converts the light received in digital electrical signal.

The transducer function in the Fleisch and Lilly neumotachometers is also performed in two steps. The airflow that passes through the neumotachometer produces a pressure drop that it is converted to an electrical signal by means of a pressure transducer.

3.1. TURBINE

The turbine type is axial, with two helix-shape stators and a rotor made with a rectangular plane blade. The physical shape of the stators makes the airflow that cross the turbine turns. This spin is the responsible that the blade turns. The functioning of the turbine is based in the Fluid Mechanics, especially in the Turbo-machine theory. Applying this theory, the angle that the rotor turns is directly proportional to the fluid volume that crosses the turbine and the proportion constant depends on the physical shape of the turbine.

3.2. TURBINE TURN DETECTOR

The turbine turn detector has three pairs of emitter diode and phototransistor of infrared light (invisible) that are located conveniently to detect the rotor turns and its direction. The beam interruption number is equal to the accumulated angle of rotor turning and therefore, the volume that has crossed the turbine. The phototransistor gives a digital electrical signal that is directly acquired by the microprocessor.

3.3. FLEISCH NEUMOTACHOMETER

The Fleisch neumotachometer principle is based in measuring the pressure drop obtained between the extremes of an obstruction, which permits the air, passes in a quasi-capillar mode. Applying then the Poiseuille law, la relationship between the flow and pressure is linear:

PRESSURE = constant. x FLOW

In the Fleisch neumotachometer, multiple capillar tubes make the obstruction and every one of them has a resistance to the airflow that produces a pressure drop between extremes.
The reason of using so many tubes and their small diameter is the air crosses the obstruction in laminar mode. In this mode the relationship between flow and pressure for the greater flow range possible without turbulence phenomena.

The flows produced in the forced spirometric tests are turbulent. It is interesting to obtain a correct measure that the flow will be laminar in the resistor and this is achieved straightening the tube diameter.
Contrary, the norms say that this resistance to the airflow should be under a limit to avoid modifying the test measure.

The best solution is using a high number of small tubes, then the flow is laminar when crosses the tubes and the total resistance is low enough to not modify the measure.

Actually, the response of Fleisch neumotachometer is linear at low flow rates, varying gradually to a quadratic realtionship in high flow rates when it is turbulent. This error is about 2% for flows from 0 to 12 l/s. Nevertheless, there are two flow linearizers that reduce the error. These devices are two metallic grid cones. Furthermore, the software includes a linearization function that improves the measure.

To avoid the condensation and to not change the linear characteristics, the neumotachometer is heated to a temperature of 37ºC.

3.4. LILLY NEUMOTACHOMETER

The Lilly neumotachometer consists on an obstruction or resistor to the airflow made of a grid. In this neumotachometer, the airflow is turbulent, so the relationship between flow and pressure is quadratic not linear:

Pressure = constant1 x $FLOW^2$ + constant2 x FLOW.

In this case linearizing by software is a must in a more complex way than a Fleisch transducer. Nevertheless its simplicity allows building a cheaper neumotachometer and also a disposable unit.

3.5. DIFFERENCIAL MANOMETER

The Fleisch and Lilly neumotachometers transform the airflow in a pressure drop. The next step is to convert the pressure drop in electrical signal. To do this a differential manometer is used. The type of the pressure transducers that are included

in Fleisch and Lilly neumotachometers of DATOSPIR 120 is semiconductor with internal temperature compensation.

3.6. FILTERS AND AMPLIFIERS

The analogue signal, which the neumotachometer pressure transducer gives, shuold be conditioned before being digitalized and processed. This conditioning stage has an amplifier that adapts the range of the transducer to the range of the digitalizer and a filter that reduces the unwanted noise. This filter limits the bandpass from 0 to 15 Hz.

3.7. ANALOG/DIGITAL CONVERTER

The analogue to digital converter samples the analogue signal when the processor orders it, and quantifies the value at its input (in this case the pressure transducer signal) giving at its output a numeric digital word.
The converter used at **DATOSPIR-110/120** has 12 bits, so it has 4096 levels for the pressure signal. The 2048 upper levels are used for the expiratory flows and the 2048 bottom levels are used for inspiratory flows.

The resolution and range of the converter meet or exceed the international organisms requirements.

3.8. MICROPROCESSOR

3.8.1. PHYSICAL DESCRIPTION

Some electronic devices that store, manage, receive and transmit information compose the microprocessor system. It can be divided in some parts:

Program of basic hardware control (BIOS) that is located in 32 Kbytes-EPROM.

Spirometry, Management Program and Test Database that are located in 1Mbyte FLASH memory.

No-volatile 128 Kbytes RAM memory that storesthe device configuration, status variables and calibration database.

Central Processing Unit (CPU).

External Communication Controller.

Clock-Calendar.

3.8.2. PROGRAM

The control program is developed in assembler language and C high level language. This characteristic assures a fast time control and structured programming. It is divided in two parts, the bios in EPROM and the application in FLASH memory.

3.8.3. MEMORY

The temporal data storing, device configuration and calibration database capacity is 128 Kbytes in non-volatile RAM. The Test Database has a maximum capacity of 320KB and it is located in FLASH memory.

3.8.4. CPU

This device manages and executes the process that is codified in instructions that compounds the program. The CPU used is the HITACHI™ 's H8/532 microcontroller.

3.8.5. CONTROLLERS

They transfer information between the CPU and the rest of devices as the keyboard, display and printer. They are integrated in the circuit of the microcontroller with the exception of the serial communications interface and the display controller.

3.8.6. QUALITATIVE DESCRIPTION

The control program is the responsible for the treatment of the spirometry signal meet the requirements of the standards, taking especially care of calculation of:

Determination of start of expiration
The start of test is determined by surpassing a flow threshold of approximately 100ml/s but the values recorded before are not discarded.

Retrograde extrapolation
The determination of start of FVC manoeuvre is performed by a retrograde extrapolation as A.T.S. and S.E.P.A.R. criteria.

Determination of end of manoeuvre
The end of FVC manoeuvre is carried out following A.T.S. criteria, that means the accumulated volume in the last second is less than 25ml.

Calibration program

Turbine

The posible aging or the accumulated dirt of the turbine transducer may do an inaccurate measure. To check the turbine measures properly, the system includes a simple check-up procedure based in measuring the known volume of a calibration syringe.

Neumotachometers

The relationship between the pressure drop and the airflow in the neumotachometers depends on the gas viscosity. This viscosity is also depending of atmospheric conditions of temperature, pressure and humidity. This is the reason for calibrating the neumotachometer every day or every time that atmospheric conditions change. Analysing the relative importance of the factors, the main factor is temperature, followed by humidity.

4. SPIROMETRY TECHNIQUE (*)

4.1. PROCEDURE

(*) The following is an extract from “NORMATIVA PARA LA ESPIROMETRIA FORZADA” (FORCED SPIROMETRY REGULATIONS) SEPAR recommendations, Nº 1.

Forced spirometry must be carried out by the patient sitting bolt upright, having his nose blocked by nasal tweezers. The technician must lean his hand against the patient’s shoulder to prevent the patient leaning forward during expiration time. The mouthpiece must be deformation-proof in order to avoid artefacts caused by the reduction of light, due to bite, during forced expiration. Soft mouthpieces must be shortened in order to increase its consistency. The spirometry will always involve a minimum of three forced expiration operations, and a maximum of eight if they are not considered suitable. Surpassing this limit will mean pointless patient tiredness and a loss of time for the technician.

For the evaluation of the spirometry carried out in decubitus position you must bear in mind that under these conditions the obtained data are inferior by 10%, approximately, to the ones obtained with the patient sitting. In patients with diaphragmatic or neuromuscular pathology the difference between both possitions can be 40-60%, which makes of the observation a useful piece of information in the valuation of the repercussion of this pathology.

When you work with the pneumotachometer the operation can be reduced exclusively to the maximum expiration from the maximum inspiration possition. The accuracy of an operation will be judged by its onset, course and conclusion, by observing the patient and the graph layout. The onset must produce a sudden, neat defection. The course must draw a concavity curve going smoothly upwards without any rectification. The conclusion should be asintotic and not perpendicular or sudden.

Measurement of expired volume during a force operation is influenced by the selection of its starting point. This obliges you to choose an onset criterion and to constantly maintain it. The so called retrograde extrapolation is the most consistent and welcomed method by European and American laboratories, and it is the choice, unless other methods prove as good as this one or with similar results. The volume extrapolated by this process must be inferior to 5% of FVC or 100 ml, wichever is greater.

In order to achieve a good spirometry the technician should make sure that the patient’s effort is maximum, that the onset is correct, and that there is not any caughing or Valsalva operation due to glottis closing. Special attention must also be paid to avoiding excesively early ending of expiration, which would be detected at the end of the curve. This would reach too perpendicularly the horizontal base line. Sometimes, the patient, inadvertenly, partially blocks the mouthpiece with his tounge or his false teeth.

As an essential criterion, the two best expirations out of the three best acceptable curves can differ between them up to 5% or ± 100 ml in the FVC, wichever is greater.

The best effort cannot be determined only by simple inspection of the spirometric curve.
Measurements must be checked in order to determine the maximum values. The independent selection of FVC and FEV1 sometimes provokes a slight increase of variability, since factors such as learning, fatigue or bronchospasm come into play induced by the expiration. It is not necessary to discard the best FEV1 when the operation it comes from has finished permaturely. On the other hand, the FEF25-75% is influenced by the selected curve vital capacity. Mistaken high values may result if an operation with trim vital capacity minor than the individual's actual one has been selected.

Aparently, the most practical way to carry out its calculation is by choosing the operation containing the maximum Vital Capacity and FEV1 add among the three selected.

4.2. CALIBRATIONS

Apart from the calibration procedures incorporated to the unit by the manufacturer for a quick checking of the running of circuits and basic machinery of the pneumotachometer, the unit should admit check out by means of applying external signals. These signals must bear the maximum similarity to the biological sign for which the instruments have been designed, i.e forced expiration. This is not always possible but, al least, some of the biological signal elements, such as volume and flow, should be reproduced either together or separately. For this purpose syringes with several litres capacity provide a suitable signal, and flow generators are good for valuating the accuracy and errors in the flow measurament. The so-called explosive descompressor is one of the most practical calibration machines. It consists of a chamber of 4 or 5 litres pressured at 1 athmosphera, provided with sudden oppening for the violent expulsion of a volume identical to the one inside the chamber. In this way an individual's forced expiration can be simulated. By placing suitable resistances with different obstruction rate in the exit tube, the signal is similar to that of a patient with slight, moderate, or severe obstruction to air flow.

Therefore, it checks both the volume and the flow measurements. Building a machine of these characteristics is easy, but if you
cannot build one you can check the machine operating conditions by means of using "control individuals", that is to say, people connected with the laboratory who are willing to cooperate. They can carry out a correct expirometry easily and with little variability (chart I) in such a way that they can reproduce their expirometry periodically and compare it to previous data. In this way, errors, that are necessarily of a large magnitude, can be detected. The espirometry variability prevents the detection of small differences in volume and flow measurement (see chart I).

“In normal working conditions calibration by means of volume signal provided by a hand syringe should be carried out daily. The signal provided by the syringe should be produced with different thrusts in order to verify that the flow read-out maintains a rectilinear response, since the machine must integrate the signal always in the same volume, i.e. the one provided by the syringe signal. How sudden the injecting operation may be does not matter as long as it does not surpasses the upper limit of flow rank accurately measured by the machine itself (proximity to actual value).

The calibration with dinamic gauged signal provided by the explosive decompressor or spirometry measurement in control individuals cannot be carried out so often. As for tachometers, it is advisable to carry it out once a fortnight with the decompressor. As spirometries with control individuals are more complicated and less available, it cannot be carried out more often than once a month unless you have suspicion of malfunction.

Chart I Variability of the spirometry in a healthy person.

Variables	**age:6-20 years**	**20-70 years**
FVC	1,9	2,2
FEV1	2,2	2,2
FEF 25-75%	6,5	4,8
MEF 50%FVC	5,3	4,7

* Values corresponding to 33 healthy volunteers.
** Values of 20 healthy adults.

4.3. REFERENCE VALUES FOR FORCED SPIROMETRY “SEPAR”

The DATOSPIR-110/120 spirometer incorporates the tables of reference of the SEPAR, except if the equipment is destined to outside of the Spanish territory. In this case, unless otherwise stated, the ECCS-93 reference values for adults between 18 and 70 years are incorporated.

Variable	Sex	Ecuation (6-20 years)	R	SEE
FVC	M	0.02800T + 0.03451P + 0.05728E - 3.21	0.947	0.443
	F	0.03049T + 0.02220P + 0.03550E - 3.04	0.935	0.313
FEV1	M	0.02483T + 0.02266P + 0.07148E - 2.91	0.945	0.378
	F	0.02866T + 0.01713P + 0.02955E - 2.87	0.940	0.263
*FEV1/FVC %	M	0.593E - 0.113P +81.60		
	F	0.026T +82.60		
FEF 25-75%	M	0.038T + 0.140E - 4.33	0.832	0.796
	F	0.046T + 0.051E - 4.30	0.789	0.651
PEF	M	0.075T + 0.275E - 9.08	0.907	1.073
	F	0.073T + 0.134E - 7.57	0.879	0.831
MEF 50%FVC	M	0.017T + 0.157E + 0.029P - 2.17	0.856	0.811
	F	0.046T + 0.067E - 4.17	0.803	0.669
MEF 25%FVC	M	0.024T + 0.066E - 2.61	0.760	0.562
	F	0.027T + 0.032E - 2.68	0.709	0.507

Variable	Sex	Ecuation (20-70 years)	R	SEE
FVC	M	0.0678T - 0.0147E - 6.05	0.72	0.530
	F	0.0454T - 0.0211E - 2.83	0.75	0.403
FEV1	M	0.0499T - 0.0211E - 3.84	0.75	0.444
	F	0.0317T - 0.0250E - 1.23	0.82	0.307
*FEV1/FVC %	M	- 0.1902E + 85.58		
	F	- 0.224E - 0.1126P + 94.88		
FEF 25-75%	M	0.0392T - 0.0430E - 1.16	0.55	1.000
	F	0.0230T - 0.0456E + 1.11	0.70	0.680
PEF	M	0.0945T - 0.0209E - 5.77	0.47	1.470
	F	0.0488T - 0.0304E + 0.35	0.47	1.040
MEF 50%FVC	M	0.0517T - 0.0397E - 2.40	0.47	1.300
	F	0.0242T - 0.0418E + 1.62	0.56	0.925
MEF 25%FVC	M	0.0190T - 0.0356E - 0.14	0.63	0.620
	F	0.02T - 0.031E - 0.0062P - 0.21	0.76	0.405
*FEV1/PEF	M	6.64		
	F	7.77		
*FEV1/FEV0.5	M	1.45		
	F	1.50		
*MEF50/MIF50	M	0.66		
	F	0.88		
*PEF/PIF	M	1.39		
	F	1.42		
*FEV1/FIV1	M	0.80		
	F	0.89		

M: Male; F: female
R: multiple correlation coefficient
SEE: typical error of the estimation
T: size (cm); P: weight (Kg); E: age (years)

The parameters with an asterisk (*) are not related in the reference standard of the SEPAR.

4.4. REFERENCE VALUES FOR FORCED SPIROMETRY "ERS.93"

(Standardized Lung Function Testing, Official Statement of the European Respiratory Society, Luxembourg 1993)

Variable	Sex	Ecuation (18-70 years)	RSD	1.64RSD
FVC	M	5.76H - 0.026A - 4.34	0.61	1.00
	F	4.43H - 0.026A - 2.89	0.43	0.71
FEV1	M	4.30H - 0.029A - 2.49	0.51	0.84
	F	3.95H - 0.025A - 2.60	0.38	0.62
FEV1/FVC %	M	- 0.18A +87.21	7.17	11.80
	F	- 0.19A +89.10	6.51	10.70
FEF 25-75%	M	1.94H - 0.043A + 2.70	1.04	1.71
	F	1.25H - 0.034A + 2.92	0.85	1.40
PEF	M	6.14H - 0.043A + 0.15	1.21	1.99
	F	5.50H - 0.030A - 1.11	0.90	1.48
MEF 75%FVC	M	5.46H - 0.029A - 0.47	1.71	2.81
	F	3.22H - 0.025A + 1.60	1.35	2.22
MEF 50%FVC	M	3.79H - 0.031A - 0.35	1.32	2.17
	F	2.45H - 0.025A + 1.16	1.10	1.81
MEF 25%FVC	M	2.61H - 0.026A - 1.34	0.78	1.28
	F	1.05H - 0.025A + 1.11	0.69	1.13

M: Male; F: female
H: hight (m); A: age (years)
RSD: (Residual Standard Deviation)

Ages from 18-24 years are computed as 25 years for all references.

Between 6 and 18 years are taken the tables of the SEPAR, unless others are indicated.

IMPORTANT ADVICE

A ETHNIC FACTOR can be introduced in the DATOSPIR-110/120 Spirometer. This factor modifies the reference values for different people groups and it can be in the range from 80 % to 120 % of the reference values, being a 100 % the value of the tables.

4.5. OTHER REFERENCE VALUES AND AGE RANGE

Aside SEPAR and CECA references, the spirometer has also the following references:

- ECCS (ERS) 7 to 70 (For ages between 6 and 18 are used SEPAR values and for ages >70 , reference values are extrapolated)
- KNUDSON 6 to 84 (For ages <6 & >84, reference values are extrapolated)
- CRAPO 4 to 91 (For ages >91, reference values are extrapolated)
- ZAPLETAL 4 to 17 years.
- MORRIS 24 to 100 years.
- AUSTRIA 6 to 90 (For 4 years and ages>90, reference values are extrapolated)
- GUTIERREZ (CHILE) 5 to 100 (For 4 years, reference values are extrapolated)
- BRAZIL 6 to 76 (For ages <6 & >76, reference values are extrapolated)
- POLGAR/WENG 4 to 100 years.
- HANKINSON 4 to 100 years
- PÉREZ/PADILLA (MEXICO) 7 to 100 (For ages <7 years, reference values are extrapolated)
- A.J. CRUZ (MEXICO) 17 to 64 (For ages <17 years, reference values are extrapolated)

5. PRESERVATION, PREVENTIVE AND CORRECTIVE MAINTENANCE

The **DATOSPIR-110/120** spirometer requires, as every equipment, and especially if it is for medical applications even more, a preservation or maintenance directed, in the first place, to the safety of the patient, operator and the environment and, secondly, to insure the reliability and accuracy of the functions for which it has been developed. All this comports a series of routines which must be executed.

5.1. PRESERVATION

Preservation is the action directed to maintain the equipment in a correct operating condition, and the person performing this does not need any special technical quality, except for the proper knowledge of the functions and manipulation of the equipment. It should be normally done by the same user of the equipment. The operations to be carried out are as follows:

5.1.1. CLEANING OF THE NEUMOTACHOMETER OR TURBINE TRANSDUCER

A- FLEISCH NEUMOTACHOMETER

The neumotachometer is the most delicate part of the spirometer and, therefore, you must have special care in handling of the same.

Regard being had to the fact that the neumotachometer is the part exposed directly to the patient, it is necessary to maintain it in perfect physical and hygienical conditions. To this purpose, proceed as follows:

1. Take off the rubber nozzles and extract the linealizing cones. Fig. 5.1.1.

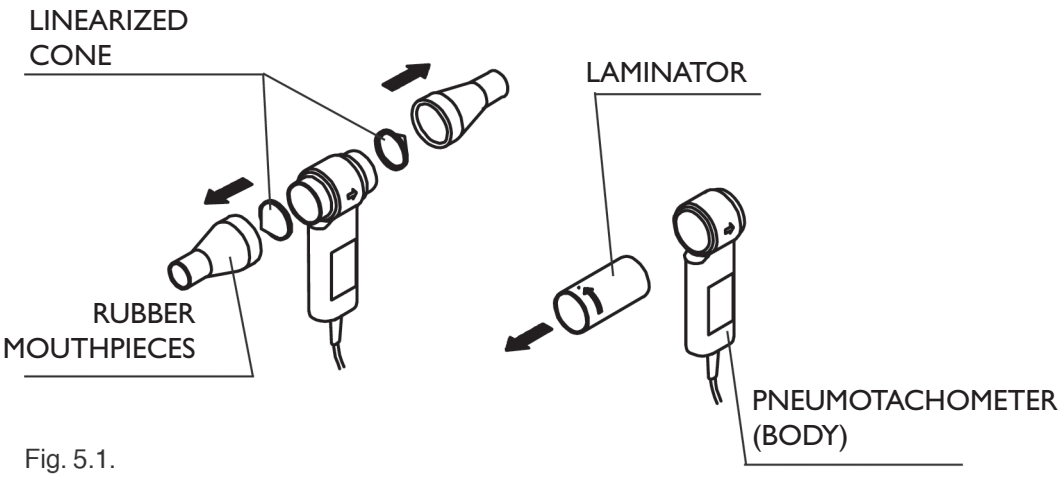


Fig. 5.1.

2. Extract the laminator turning to the left and taking it out as shown in Fig. 5.1.1.

3. Wash the rubber nozzles, cones and laminator with soap. Regard being had to the structure of the laminator, the procedure must be very careful.

4. After rinsing, it is convenient to rinse again with destilled water to avoid deposits of salts, especially on the flux laminator.

5. The final drying is carried out with a simple electric dryer, such as those employed for hair drying, which allows to considerably accelerate the process. Procure that the laminator is not exposed to temperatures of more than 70ºC. For this reason, put the dryer not nearer to the laminator than 15 or 20 cm. and do not keep it during a long time.

6. Clean internal and external parts of neumotachometer with a dry or slightly water-moistened cloth, drying thereafter the remanent humidity. You must pay special attention to that no liquid penetrates inside nor to the connectors or connections. See fig. 5.1.2.

Don't use abrasive substances or solvents.

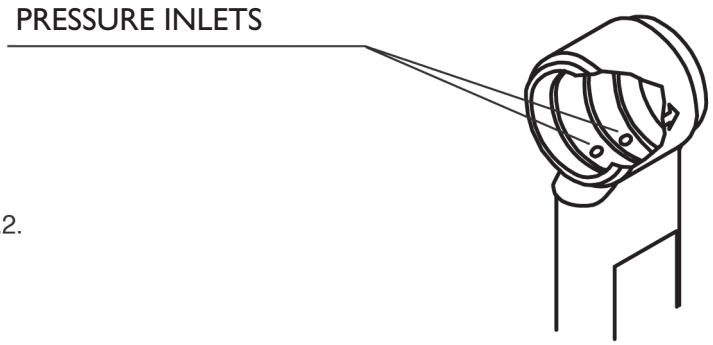


Fig.5.2.

7. Assemble the group again according to the Fig. 5.1.3.

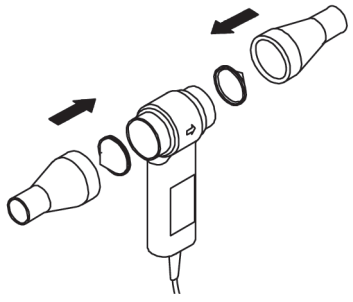


Fig.5.3.

If you suspect a microbian contamination, it is necessary to use antiseptics in solution or more complex sterilization procedures.

CAUTION

DO NOT SUBMIT THE NEUMOTACHOMETER TO TEMPERATURES EXCEEDING 70ºC.

B- TURBINE TRANSDUCER

As the turbine is the piece directly exposed to the patient, it is necessary to maintain it in perfect physical and hygienical conditions. To this purpose, proceed as follows:

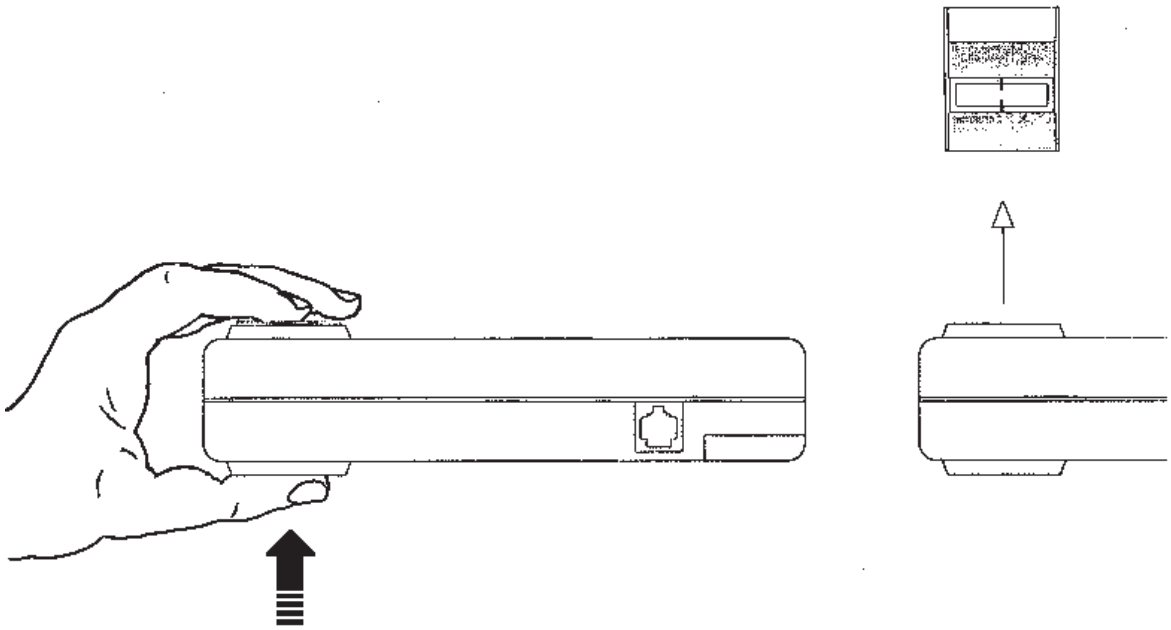


Fig. 5.4.

1-The turbine can be disassembled from the device housing by pressing smoothly to take it off.

2-The Turbine can be washed with soap and water. Do not use solvents, alcohols, etc that can damage the components. Since the reliability of the turbine depends on it, you should take care not to damage it.

3-Once cleaned it with clear water, it is convenient to avoid the salt sediments by cleaning it again with distilled water.

4-The final dry can be made with warm air.

5-Assemble the turbine in the housing again.

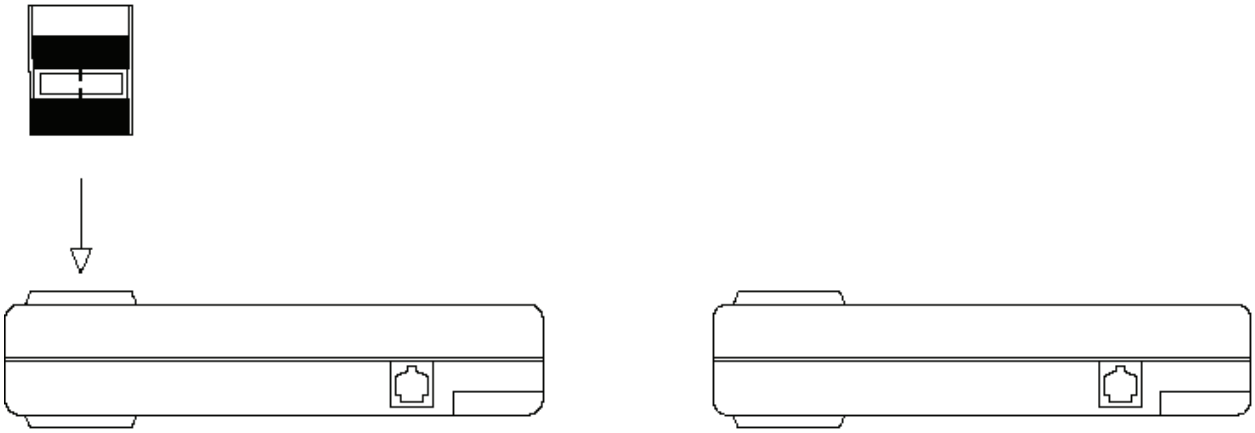


Fig. 5.5.

If you suspect a microbian contamination, it is necessary to use antiseptics in solution or more complex sterilizing procedures, for example, the immersion in a solution of Dietilentriamine or Sodium Dichloroisocianurate for 10 to 30 minutes .

PRECAUTION
DO NOT EXPOSE THE TURBINE TO TEMPERATURES EXCEEDING 60 ºC OR BELOW 0 ºC. DO NOT USE SOLVENTS, ALCOHOLS OR OTHER SIMILAR SUBSTANCES DURING ITS CLEANING, WHICH MAY DAMAGE IT.

C- Disposable Transducer

This transducer does not need any kind of cleaning. It is thought so it can be throwed away once the patient is done with the tests.
The disposable transducers are for a single use only. Reutilization of the disposables transducers gives a risk of crossed infection. In addition, the use of disinfectant products can affect the transducer's mesh and give a loss of accuracy of the measurement.

REUTILIZATION OF THE TRANSDUCER GIVES A RISK OF REINFECTION OR CROSSED INFECTION.

THE USE OF DISINFECTANT PRODUCTS CAN AFFECT THE TRANSDUCER'S MESH AND GIVE A LOSS OF ACCURACY IN THE MEASUREMENT.

The handle and the housing of the disposable transducer can be cleaned with a dry cloth or slightly moistened with water, drying thereafter the remanent humidity trying to avoid the water to be introduced in the pressure inlets. This operation must be done with the transducer cable above the transducer itself, thus avoiding the introduction of strange elements in the pressure inlets.

5.1.2. INTERNAL PRINTER

- Collocation of the paper

For this operation, it is necessary to proceed as detailed in the paragraph 1.5.4. COLOCATION OF THE PAPER

5.1.3. SPIROMETER

The spirometer is smoothly wiped with a dry or slightly water-moistened cloth, drying thereafter the remanent humidity. Take care that no liquid penetrates inside or in the connectors or connections.

Do not use abrasive substances or solvents.

5.2. PREVENTIVE MAINTENANCE

The preventive maintenance consists of all those technical actions directed to keep the device in a good condition of use.

Four types of preventive maintenance are established:

1. The equipment, every time it starts up, checks some parts of itself.

2. A second type, which can be carried out by the same user, consists of a periodical supervision of the aspect of the different interconnections and other external elements of the system. In this supervision, you will verify that all the interconnections are perfectly connected and all the cables and/or connectors, as well as other elements do not present breakage or external damages.

In case of detecting some anomaly, which the user cannot resolve by him, inform the technical service so that they proceed to check or repair it.

3. The user can access to the **Maintenance Program** to adjust and/or verify some parts of the device as it is detailed in paragraph 1.15

4. A fourth type consists on a general technical verification of the safety systems, adjustments, functions, etc., which configure the system.

THIS TECHNICAL VERIFICATION WILL BE DONE WITH AN ANNUAL PERIODICITY, and according to the Manufacturer's Verification and Adjustment Procedure of the **DATOSPIR-110/120**. Qualified technical personnel of the maintenance department of the center, technical service of your distributor or the manufacturer must perform this type of operations.

In any case, **SIBEL S.A.**, as the manufacturer, must authorize in writing, at least

during the warranty period, the corresponding technical service, allowing them to make such maintenance. And in any case, no responsibility for damage, misfunction, etc. will be admitted, which might arise as a result of a defective maintenance by persons not belonging to **SIBEL S.A.**

5.3. CORRECTIVE MAINTENANCE

The corrective maintenance consists of putting the device in a good condition of use which, for bad operation or bad use, has been put out of service and which is necessary to repair.

In case of detecting in the system a break-down which impedes its normal use, disconnect the device from the power supply and contact the corresponding technical service, specifying as detailed as possible the type of anomaly detected.

6. MODIFICATIONS

ANNEX1. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions

DATOSPIR 110/120 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidance
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	DATOSPIR 110/120 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Grupo 1 Clase B	DATOSPIR 110/120 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Yes	

Guidance and manufacturer's declaration – electromagnetic immunity			
DATOSPIR 110/120 is intended for use in the electromagnetic environment specified below. The costumer or the user of DATOSPIR 110/120 should assure that it is used in such an environment.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	±1 kV differential ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DATOSPIR 110/120 requires continued operation during power mains interruptions, it is recommended that the DATOSPIR 110/120 be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

DATOSPIR 110/120 is intended for use in the electromagnetic environment specified below. The costumer or the user of DATOSPIR 110/120 should assure that it is used in such an environment.

Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of DATOSPIR 110/120, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN-IEC 61000-4-6	3 Vrms 150KHz to 80 MHz	3 Vrms (Disposable and turbine) 2Vrms (Fleisch)	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (Disposable and turbine) 1V/m (Fleisch)	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1. At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which DATOSPIR 110/120 is used exceeds the applicable RF compliance level above, DATOSPIR 110/120 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such reorienting or relocating DATOSPIR 110/120.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and DATOSPIR 110/120

DATOSPIR 110/120 is intended for use in an electronic environment in which radiated RF disturbances are controlled. The costumer or the user of DATOSPIR 110/120 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DATOSPIR 110/120 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter	**Separation distance according to frequency of transmitter** m		
	De 150 kHz a 80 MHz	**De 80 MHz a 800 MHz**	**800 MHz to 2.5 GHz**
W	$d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 800 MHz, the separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absortion and reflection from structures, objects and people.

ANNEX2. COMPLIANCE WITH THE DATA PROTECTION ACT (LOPD)

COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC.

Requirements specifically affecting the use of the DATOSPIR 110/120 Spirometer

This section seeks to ensure user compliance with the current data protection legislation in relation to the use of this equipment. A brief description is given as to how the DATOSPIR 110/120 Spirometer must be handled to comply with the requirements of this act.

IMPORTANT WARNING

• According to current legislation, the user of this equipment is the only party responsible for saving and processing the details of his patients according to the Law.

• Observance of the recommendations included in this section under no circumstances guarantees the full adaptation of the user's activity to the data protection regulation.

Other important issues

• Printing documents:

In the event of saving paper printouts containing patient details, these documents must be properly stored so that only duly authorised personnel have access to them. Furthermore, in the event of users deciding to dispose of the printed documents, their effective physical destruction must be ensured to avoid unauthorised access thereto.

• Data transmission:

The DATOSPIR 110/120 spirometer can transmit files containing patient details via PC connection so that work can be subsequently carried out on them using the W20 Spirometry Software. This software is also compliant with the Data Protection Act, as explained in the W20 Spirometry Software User's Manual.